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No. 08-

IN THE

Supreme Court of the United States

GILEAD SCIENCES, INC., *et al.*,
Petitioners,

v.

TRENT ST. CLARE, *et al.*,
Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

Whether a plaintiff in a "fraud on the market" case under Section 10(b) of the Securities Exchange Act must plead facts with sufficient particularity to support a reasonable, non-speculative belief that the plaintiff ultimately can prove loss causation.

PARTIES TO THE PROCEEDING

Petitioners, defendants-appellees below, are Gilead Sciences, Inc., John C. Martin, John F. Milligan, Mark L. Perry, Norbert W. Bischofberger, Anthony Carraciolo and William A. Lee. The individual petitioners are current and former executive officers of Gilead Sciences, Inc. Petitioner Gilead Sciences, Inc. is a publicly traded corporation with no parent corporation, and no publicly held company owns 10% or more of its stock.

Respondents are Trent St. Clare and Terry Johnson, appellants appointed as lead plaintiffs below, purporting to act on behalf of themselves and a putative class of all persons similarly situated, consisting of purchasers of Gilead Sciences securities between July 14, 2003 and October 28, 2003. No class has been certified.

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Petitioners Gilead Sciences, Inc. ("Gilead"), John C. Martin, John F. Milligan, Mark L. Perry, Norbert W. Bischofberger, Anthony Carraciolo and William A. Lee respectfully request that a writ of certiorari issue to review the judgment of the United States Court of Appeals for the Ninth Circuit in this case.

OPINIONS BELOW

The opinion of the Ninth Circuit was entered on August 11, 2008, and is reported at 536 F.3d 1049 (9th Cir. 2008). It is included in the Appendix ("App.") at 1a-20a. The Order denying Petitioners' motion for rehearing or rehearing *en banc*, entered on October 9, 2008, is included in the Appendix at 87a-88a. The opinion and order of the United States District Court for the Northern District of California dismissing

respondents' Fourth Amended Class Action Complaint ("Fourth Amended Complaint"), was entered on May 12, 2006, and is included in the Appendix at 21a-41a. That opinion is available at 2006 WL 1320466. The opinion and order of the district court dismissing respondents' Third Amended Class Action Complaint ("Third Amended Complaint"), was entered on October 11, 2005, and is included in the Appendix at 42a-61a. The opinion and order of the United States District Court for the Northern District of California dismissing respondents' Consolidated Amended Class Action Complaint ("Amended Complaint"), was entered on January 26, 2005, and is included in the Appendix at 62a-86a.

JURISDICTION

The court of appeals issued its opinion on August 11, 2008. Petitioners timely sought rehearing, which was denied on October 9, 2008. App. 87a-88a. On December 23, 2008, Justice Kennedy extended the time in which to file this petition to February 6, 2009. The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

STATUTORY PROVISION INVOLVED

Section 21D of the Securities Exchange Act of 1934, 15 U.S.C. § 78u-4, was added by the Private Securities Litigation Reform Act of 1995 ("PSLRA"), Pub. L. No. 104-67, 109 Stat. 737, 747. Section 21D provides, in pertinent part, as follows:

> (b)(4) LOSS CAUSATION. In any private action arising under this chapter, the plaintiff shall have the burden of proving that the act or omission of the defendant alleged to violate this

chapter caused the loss for which the plaintiff seeks to recover damages.

STATEMENT OF THE CASE

This case presents a split of authority concerning a question left open by this Court in *Dura Pharmaceuticals, Inc.* v. *Broudo*, 544 U.S. 336 (2005): the pleading standard for alleging "loss causation" in a claim seeking damages for securities fraud. In *Dura*, this Court made clear that under Section 10(b) and the PSLRA, a plaintiff bears the burden of proving (1) that the price decline for which damages are sought occurred *after* the alleged fraud was revealed to the market, and (2) that the losses claimed are attributable only to that fraud, and not to other potentially confounding conditions or events unrelated to the fraud. *Id.* at 342-43. This Court concluded that the complaint in *Dura* failed to articulate the required *theory* of loss causation. The Court declined the invitation of the Solicitor General in *Dura* to define the pleading standard further.

Since *Dura*, lower courts have struggled with the proper pleading standard applicable to allegations of loss causation in a securities fraud complaint. Three distinct approaches have now emerged. The Fifth and Seventh Circuits have applied the particularity requirement of Federal Rule of Civil Procedure 9(b) to such pleadings. *Tricontinental Indus., Ltd.* v. *PricewaterhouseCoopers, LLP*, 475 F.3d 824, 839 n. 10, 842-43 (7th Cir. 2007); *Catogas* v. *Cyberonics, Inc.*, 292 F. App'x 311, 312-14 (5th Cir. 2008) (per curiam). The Second, Fourth and Eighth Circuits have stopped short of expressly applying Rule 9(b), but nonetheless have required that a complaint contain "sufficient factual information to provide the 'grounds' on which the claim rests, and to raise a

right to relief above a speculative level." *Schaaf* v. *Residential Funding Corp.*, 517 F.3d 544, 549 (8th Cir.) (quotation omitted), *cert. denied*, 129 S. Ct. 222 (2008); *Lattanzio* v. *Deloitte & Touche LLP*, 476 F.3d 147, 158 (2d Cir. 2007); *Teachers' Ret. Sys.* v. *Hunter*, 477 F.3d 162, 186 (4th Cir. 2007). Collectively, these courts have not allowed securities fraud complaints to survive without factual allegations providing a concrete reasonable basis to believe that the plaintiff ultimately can prove each step in the proposed chain of causation. Instead, as contemplated by the PSLRA and this Court's pleading decisions, all five Circuits require district judges to act as gatekeepers to prevent cases from going forward to discovery on the basis of sheer speculation and lawyer's argument.

By contrast, the Ninth Circuit, in this case, adopted a standard far more lenient than any other court, requiring only that the plaintiff articulate a theory of loss causation that is not "per se implausible." App. 19a.[1] Under the Ninth Circuit's approach, the plaintiff may survive a motion to dismiss merely by *asserting* that the stock drop occurred after the fraud was revealed without having to provide any factual basis to believe that the market ever learned of the fraud, and without even suggesting any factual grounds to believe that potentially confounding causes can be isolated and controlled. In the Ninth Circuit's telling, "so long as the plaintiff alleges facts that support a theory that is not facially implausible, the court's skepticism is best reserved for later stages

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[1] *See also Metzler Inv. GmbH* v. *Corinthian Colls., Inc.*, 540 F.3d 1049, 1062 (9th Cir. 2008) (applying Rule 8 standard); *Berson* v. *Applied Signal Tech., Inc.*, 527 F.3d 982, 989 90 (9th Cir. 2008) (purporting to apply Rule 9(b) but finding loss causation allegations sufficient where they gave "notice" to defendants).

of the proceedings." *Id.* at 17a. That is, only in the Ninth Circuit are the district courts forbidden to act as gatekeepers.

This low pleading threshold threatens to undermine this Court's decision in *Dura*. As the Court recognized, the securities laws should not "permit a plaintiff 'with a largely groundless claim to simply take up the time of a number of other people, with the right to do so representing an *in terrorem* increment of the settlement value, rather than a reasonably founded hope that the [discovery] process will reveal relevant evidence.'" *Dura*, 544 U.S. at 347 (alteration in original) (quoting *Blue Chip Stamps* v. *Manor Drug Stores*, 421 U.S. 723, 741 (1975)). The Ninth Circuit's decision permits precisely that.

A. Prescription Drug Industry Background.

Petitioner Gilead is a biopharmaceutical company that discovers, develops, and commercializes therapeutics for the care of patients with life-threatening diseases. At the relevant time, Gilead marketed six products, including Viread, a groundbreaking antiretroviral drug used to treat HIV/AIDS, first introduced in 2001. The individual petitioners were at all relevant times officers of Gilead.

FDA rules require a drug manufacturer to market a drug only for uses approved by the FDA. But federal law does not prohibit physicians from prescribing a drug for so-called "off-label" uses that have not been approved by the FDA, or from requesting information about such uses from the manufacturer.

As with all prescription drugs, demand for Viread is created when doctors prescribe the drug for patients. However, Gilead does not typically sell directly to patients or their doctors. Rather, Gilead sells to

pharmaceutical wholesalers, three of which purchase the vast majority of all domestic Viread and supply the pharmacies that fill prescriptions for the drug. Wholesalers make much of their profit by buying large quantities of a drug before an expected manufacturer's price increase and later selling the drug at the new, higher price. Respondents allege that overstocking a product at the lower price and selling at the new price is central to the wholesalers' business model.

B. Gilead's Second And Third Quarter 2003 Earnings.

Second Quarter 2003: In the second quarter of 2003, anticipating a price increase for Viread, Gilead's wholesalers bought excess quantities of the drug, resulting in larger than normal Viread inventory levels by the end of the quarter. Plaintiffs do not allege that Gilead knew the precise amount that the inventory levels increased during the quarter; Gilead did not have access to information regarding its wholesalers' inventory levels. Understanding the difference between revenues generated by filling prescriptions (demand) and revenues generated by increasing inventory levels was important to investors. The more Viread sales that were attributable to inventory stocking, the less the true demand for the drug during the second quarter.

Beginning July 14, 2003, Gilead announced substantially increased second quarter revenues, and identified three primary causes: rising prescription levels for Viread, significant increases in U.S. wholesaler inventories of Viread in advance of an expected price increase on June 27, 2003, and a

favorable foreign currency exchange rate.[2] A Gilead press release on July 31, 2003, reported its final results for the second quarter: net quarterly revenues of $238.9 million, of which $167 million related to Viread. Gilead further announced that it anticipated that third-quarter revenues would be "at or below" those of the second quarter as the wholesalers drew down their excess inventories of Viread.

The July 31 press release also estimated that increasing inventory stocking of Viread accounted for somewhere between $25 million and $30 million of the second quarter revenues. Importantly, the release contained a warning regarding the forward-looking statements therein and specifically warned of Gilead's limited "ability to accurately estimate inventory levels as we must make a great deal of assumptions and must rely on incomplete data to make these estimations." SER 172.[3] Indeed, securities analysts during this period warned that it was difficult to tell how much of the increase was attributable to inventory stocking.

On a publicly accessible July 31 conference call following the press release, petitioner John Milligan, Gilead's Chief Financial Officer, explained to analysts and investors that Gilead expected third-quarter Viread sales to be "at or below" second-quarter sales

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[2] The European currency environment is significant because of the proportion of Viread sales outside the U.S. Gilead reported non-U.S. revenues of $107 million for Viread in the second and third quarters of 2003, compared to $174 million of U.S. sales.

[3] Material not attached to this petition, but included in the petitioners' Supplemental Excerpts of Record in the Ninth Circuit will referred to as SER ___. Material included in respondents' Excerpts of Record in the Ninth Circuit will be referred to as ER ___.

because the second-quarter results reflected wholesalers' decisions to increase their inventories of Viread:

> Of significant note, we believe that a substantial inventory build occurred in U.S. distributor channels during the second quarter as wholesalers anticipated the Viread price increase announced on June 27th. Though difficult to determine the exact figure for this inventory build, we estimate that wholesaler inventories increased by 25 to $30 million during the quarter.

(SER 179, 184)[4]

Gilead's Form 10-Q for the second quarter of 2003 confirmed the previously announced financial results. The Form 10-Q further explained the inventory overstocking: "We estimate that this higher stocking resulted in $25.0 to $30.0 million of additional sales during the second quarter, which may adversely impact sales in the third quarter as wholesalers return to more normal inventory levels and buying patterns." SER 167.

Third Quarter 2003: On October 28, 2003, Gilead announced that, as anticipated, its third-quarter Viread revenues had declined, but that both new and total prescriptions for the drug in the U.S. and Europe had increased. Gilead also disclosed that, based on newly available data, it now believed that

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[4] During the call, Dr. Milligan also stated that Gilead expected total revenue in 2003 from Viread sales to be between $550 and $600 million (up from the earlier estimate of $475-500 million). Ultimately, in January 2004, the company reported that it had met those projections with year-end reported total Viread revenues of $566 million. Respondents do not challenge the accuracy of Gilead's 2003 total sales figures.

the wholesalers' inventory build in the second quarter had been $33 million to $37 million, rather than the $25 million to $30 million previously estimated. This was perceived by the market as negative news, as it meant that the true demand for Viread (reflecting the number of patients actually using the drug) going into the third quarter had been less than previously believed.

Gilead's stock price fell $7.46 (12.5%) to $52.00 on October 29 from the closing price of $59.46 the previous day on heavy trading volume. The stock recovered nearly half that loss within one day and recovered fully within a month.

C. Respondents' Various Efforts To State A Securities Fraud Claim.

Just two weeks after the October 28 announcement, on November 10, 2003, the first complaint was filed on behalf of a putative class, alleging, as relevant here, securities fraud in violation of section 10(b) of the Securities Exchange Act of 1934 and Rule 10b-5. 15 U.S.C. § 78j(b); 17 C.F.R. § 240.10b-5. Respondents seek damages on behalf of all purchasers of Gilead stock from July 14, 2003 through October 28, 2003 based on the October 29 stock drop.

1. The original complaints filed in this action alleged only that petitioners intentionally underestimated the level at which wholesalers had stocked Viread in the second quarter of 2003. That is why the claimed class period begins July 14, 2003 (the date that Gilead originally estimated the second-quarter inventory build) and ends October 28, 2003 (the date Gilead revised that estimate upward). From the point of view of an explanation for the (short-term) drop in Gilead's stock price following the October 28 report, this theory made sense. That is precisely how

analysts at the time explained the disappointing October 28 news.

But the district court concluded that such a theory was not actionable. Respondents had not "allege[d] any facts inconsistent with the conclusion that Gilead's 2003 second quarter financial reports were made in good faith and based on the best information available at the time." Pet. App. 77a. In short, Gilead's estimate of wholesaler inventory over-stocking was wrong, but not fraudulently so. Respondents abandoned this securities fraud theory.

2. Beginning in the Consolidated Amended Complaint, filed April 30, 2004, respondents looked for a different theory to serve as the basis of their effort to recover for Gilead's temporary drop in stock value. For the first time, they alleged that defendants illegally marketed Viread "off-label," i.e., for uses that were not approved by the FDA.

Specifically, they alleged that Gilead had improperly marketed the drug for use by patients who had not yet undergone antiretroviral therapy (treatment-naïve patients) and for use by patients co-infected with HIV/AIDS and Hepatitis B. Relying on two confidential witnesses, respondents claimed that 75-95% of the two witnesses' individual sales resulted from off-label marketing, and that their personal sales data could be extrapolated to all domestic Viread sales.

Respondents also relied upon two letters Gilead received from the FDA. The first, an "Untitled FDA Letter" dated March 14, 2002, alleged that Gilead representatives made misleading oral promotional statements at a December 2001 conference by failing to include risk information when describing the drug's benefits. The second, a "Warning Letter" from

the FDA, dated July 29, 2003, notified Gilead that the FDA considered certain oral representations made by a Gilead representative at a promotional booth during a conference in April 2003 to be improper. The letter stated that the FDA was concerned that the sales representative minimized risk information, failed to disclose that Viread was approved for use only with other antiretroviral agents, and stated that it improved lipid parameters. The fact that the company had received the July 29 letter was publicly disclosed twice: by the FDA on August 7, 2003; and by Gilead, in its Form 10-Q filed with the SEC on August 14, 2003. Respondents have never alleged that the market had any adverse reaction to the disclosure of the FDA Warning Letter. In fact, Gilead's stock price rose following the FDA's public disclosure of the letter and remained unchanged after Gilead's 10-Q filing.

Prior to this Court's ruling in *Dura*, respondents alleged that Gilead's October 28 release had "tacitly admitted that demand for Viread was not as strong as investors were previously led to believe" given the proportion of second-quarter revenues attributable to wholesaler overstocking. Indeed, respondents affirmatively alleged that the purported off-label marketing scheme remained hidden from the market:

> [W]hile disclosing their reliance on wholesaler overstocking, Defendants failed to disclose that the amount of Viread sales and prescriptions was also due to their intentional, improper, and illegal marketing and promotional campaign.

SER 5 ¶ 17, 63 ¶ 18. Neither the Amended Complaint nor its immediate successor attributed the October 29 price decline, directly or indirectly, to any decline in Viread prescriptions in the third quarter of 2003.

Both of those complaints were dismissed, the latter for failure to plead loss causation.

3. It was not until their Fourth Amended Complaint that respondents, for the first time, alleged a theory that sought to connect the October 2003 drop in Gilead's stock price to the allegedly unlawful off-label marketing of Viread and the allegedly fraudulent failure to reveal the extent to which sales of Viread were based on such unlawful conduct.

The first step in respondents' newly minted theory of loss causation asserted a connection between prescriptions written for Viread and the public disclosure of the FDA letter in August 2003. Respondents alleged that the FDA letter "set in motion events that would impede Viread's sales growth and ultimately result in a sharp drop in Gilead's stock price" because it caused physicians to be "less eager" to prescribe Viread, that "[c]ompetitors were able to use the FDA Warning Letter as an argument to physicians to choose their own product over Viread," and that, consequently, prescriptions of Viread materially decreased. ER 35 ¶¶ 14-15, 85 ¶ 200, 86 ¶ 204. As noted above, however, the stock price of Gilead was not adversely affected by the public disclosure of the FDA letter, so respondents had to stretch this putative effect on Gilead's business forward in time to the October 28 earnings report. Respondents asserted that the disclosure of the FDA letter "resulted in sales and prescription[s] for the [third] quarter that did not demonstrate the strong growth that investors had come to expect." ER 86 ¶ 203.

Respondents' loss causation "theory" is really nothing more than speculation about a highly attenuated chain of causation between Gilead's

allegedly improper marketing activities and the drop in Gilead's stock in October 2003. The allegations supporting the theory are devoid of any particularized facts that would support a reasonable, non-speculative belief that respondents could ultimately prove such a theory.

First, respondents offered no basis for inferring that the market understood the disappointing October earnings report to reflect a drop in Viread prescriptions at all, much less a drop attributable to any concerns about unlawful off-label marketing. In fact, respondents do not allege that the company's disclosure, contemporaneous with the earnings report, that Viread prescriptions had actually increased in the third quarter was in any way inaccurate, and there is no allegation in the Fourth Amended Complaint that investors did not believe that disclosure. Respondents have not alleged that any doctors they interviewed ceased or reduced prescriptions of Viread during the third quarter of 2003, let alone in response to the publication of the FDA Warning Letter.

None of the public statements in the record suggests a decline in Viread prescriptions in the third quarter. Gilead's October 28 press release stated that prescriptions continued to grow. A Morgan Stanley analyst report noted that overall Viread sales were down 31% compared to the second quarter, but attributed this to wholesaler inventory stocking, just as respondents had alleged in an earlier version of their complaint. The Morgan Stanley report included a boldfaced front-page headline "**Viread Inventory the Story**," which indicated that *second quarter* "end-user demand run rates were actually lower than previously believed. Thus, while Viread demand continues to grow, it is off a lower base." ER 114-15.

A Bear Stearns analyst report calculated end-user demand rising 17% from the second quarter but similarly downgraded growth projections in light of the inventory stocking misestimation. SER 213. A chart in the Morgan Stanley report shows a consistent trend of upward growth in Viread prescriptions from October 2002-October 2003, accompanied by statistics and charts showing *increasing* prescriptions and market share for Viread. ER 116-18.

Second, and equally important, respondents have never suggested that they can isolate any putative impact of the disclosure of the allegedly unlawful off-label marketing scheme. Gilead, analysts and even the respondents themselves (in all of their earlier complaints) contemporaneously attributed the entire drop in Gilead's stock price on October 29, 2003, to the fact that Gilead was forced to increase its estimate of the degree to which its wholesalers had grown their inventories in the previous quarter and to lower sales in Europe. Respondents do not even attempt to claim that the losses they seek to recover can be segregated from these confounding conditions, conditions to which they had previously attributed the entire stock drop.

D. The District Court's Dismissal.

On May 12, 2006, the district court dismissed the Fourth Amended Complaint for failure adequately to plead loss causation under *Dura*. App. 33a-39a. Even applying Rule 8, *id.* at 36a, 39a, the court found:

> Plaintiffs' allegations regarding loss causation are simply too attenuated. . . . [T]hey require the Court to make the unreasonable inference that a public revelation on August 8 *caused* a price drop *three months later* on October 28. . . .

> . . . Even if the FDA Warning Letter caused prac-titioners to reduce their Viread supply, Plaintiffs still fail to connect that with the drop in stock price.

Id. at 34a-35a. The district court found no sign that the market was concerned about declining Viread prescription rates:

> [T]he market analyst reports . . . undermine Plaintiffs' theory that the disclosure led to a decrease in demand. The reports do not predict a decrease in demand at all. Indeed, they suggest that the demand for Viread would continue to grow.

Id. at 36a. Thus, the district court reiterated its prior conclusion that "'the record reflects that investors never actually learned the extent of Defendants' off-label marketing scheme.'" *Id.* at 35a n. 9.

Finally, the court held that the complaint failed to provide any indication that the plaintiffs could distinguish the loss attributable to the alleged fraud, from loss attributable to other, nonfraudulent factors: "the Court is left to speculate as to what portion, if any, of [the stock drop] should be attributed to the alleged misconduct and what should be attributed to other market factors." *Id.* at 39a.

E. The Ninth Circuit's Decision.

The Ninth Circuit reversed. Noting that *Dura* had left open whether Rule 9(b) applies to the loss causation element of securities fraud, the court stated that it did not need to decide whether to apply Rule 8 or Rule 9(b) because under its understanding of even the strict pleading requirements of Rule 9(b), respondents' Fourth Amended Complaint gave "'sufficient detail to give defendants ample notice of

[respondents'] loss causation theory, and to give us some assurance that the theory has a basis in fact.'" App. 14a-15a (quoting *Berson* v. *Applied Signal Tech., Inc.*, 527 F.3d 982, 989-90 (9th Cir. 2008)). Yet, the Ninth Circuit's description of that standard amounted to a substantial weakening of it: "So long as the complaint alleges facts that, if taken as true, plausibly establish loss causation, a Rule 12(b)(6) dismissal is inappropriate." App. 18a.

According to the Ninth Circuit, the October 28 press release could be considered a "corrective disclosure" that caused the public to "finally realize the impact of the off-label marketing and the Warning Letter":

> Our review of the Investors' complaint convinces us that the October drop in stock price was plausibly caused by the Warning Letter.

App. 19a. The Ninth Circuit did not fill in any of the gaps in the attenuated chain of reasoning that led the district court to dismiss the complaint for failure to plead loss causation. The complaint survived, in the Ninth Circuit's view, because the gaps in time and causal connections discussed above do "not render a plaintiff's theory of loss causation per se implausible." *Id.*

REASONS FOR GRANTING THE PETITION

Dura expressly left open the appropriate pleading standard for loss causation because the allegations in *Dura* could be dismissed even "assum[ing], at least for argument's sake, that neither the [Federal] Rules [of Civil Procedure] nor the securities statutes impose any special further requirement in respect to the pleading of proximate causation or economic loss." 544 U.S. at 346. The question whether either the

Federal Rules of Civil Procedure or the securities statutes impose "any special further requirement in respect to pleading" of loss causation now requires this Court's attention in light of the split of authority that has developed. This case provides an excellent vehicle to review the question.

1. There is now a 2-3-1 split of authority regarding the proper pleading standard for loss causation allegations in a securities fraud complaint. Two courts have indicated that Rule 9(b)'s pleading standard applies to loss causation allegations. Three other courts have not expressly concluded that Rule 9(b) applies, but have nonetheless required some form of heightened factual specificity in pleading loss causation. Finally, one court, the Ninth Circuit, follows its own path and holds that factual specificity is not required with regard to loss causation allegations, and that the articulation in a complaint of a not facially implausible *theory* of loss causation will suffice to survive a motion to dismiss.

The Fifth and Seventh Circuits have rigorously applied the Rule 9(b) standard to loss causation. In *Tricontinental*, the Seventh Circuit dismissed a Section 10(b) claim on loss causation grounds, 475 F.3d at 843-44, while allowing a related state-law negligent misrepresentation claim to proceed. The court of appeals acknowledged that both claims required proof of loss causation, but the state-law claim survived because the "negligent misrepresentation claim must be evaluated according to the pleading requirements of Rule 8, not the heightened pleading requirements of Rule 9." *Id.* at 839 n. 10. Similarly, the Fifth Circuit has required loss causation allegations to be pleaded with "particularity," as mandated under Rule 9(b). *Catogas*, 292 F. App'x at 312.

Three other Circuits, the Second, Fourth and Eighth, have not expressly relied upon Rule 9(b), but still have demanded a heightened degree of factual specificity in pleading loss causation. Decisions from both the Second and Fourth Circuits provide strong reasons to apply Rule 9(b)'s particularity requirement to loss causation allegations in a securities fraud case.[5] The Second Circuit has applied Rule 9(b) to loss causation allegations in the RICO context, holding that a plaintiff "must allege loss causation with sufficient particularity such that we can determine whether the factual basis for the claim, if proven, could support an inference of proximate cause." *First Nationwide Bank* v. *Gelt Funding Corp.*, 27 F.3d 763, 770-72 (2d Cir. 1994). Its subsequent Section 10(b) decisions, while not expressly relying on Rule 9(b), have similarly characterized the pleading threshold. See *Lattanzio*, 476 F.3d at 157-58 ("Plaintiffs have not alleged facts to show that Deloitte's misstatements, among others . . . that were much more consequential and numerous, were the proximate cause of plaintiffs' loss; nor have they alleged facts that would allow a factfinder to ascribe some rough proportion of the whole loss to Deloitte's misstatements"); *Lentell* v. *Merrill Lynch & Co.*, 396 F.3d 161, 174-77 (2d Cir. 2005) (complaint must

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[5] The Rule applies, on its face, to all of "the circumstances constituting fraud." The most natural reading of that phrase is that it incorporates all of what *Dura* called the "traditional elements" of fraud at common law, including how the fraud caused the plaintiff harm. *Dura*, 544 U.S. at 343-46. Under the canon of *expresio unius exclusio alterius*, the Rule's exception providing that the element of intent "may be alleged generally" suggests that the drafters of Rule 9(b) intended all the other traditional elements to be pleaded with particularity. *Cf. Leatherman* v. *Tarrant County Narcotics Intelligence & Coordination Unit*, 507 U.S. 163, 168 (1993).

"allege facts to establish that [the defendant's] misstatements . . . concealed the [risk] that materialized and played some part in diminishing the market value of" the company).

The Fourth Circuit has observed that "[a] strong case can be made that because loss causation is among the 'circumstances constituting fraud for which Rule 9(b) demands particularity, loss causation should be pleaded with particularity.'" *Teachers*, 477 F.3d at 185-86. The Fourth Circuit has also indicated that, at a minimum, loss causation "must [be] plead . . . with sufficient specificity to enable the court to evaluate whether the necessary causal link exists." *Id.* at 186. The Eighth Circuit, citing this Court's decision in *Twombly*, has required a plaintiff to allege "sufficient factual information to provide the 'grounds' on which the claim rests." *Schaaf*, 517 F.3d at 549.

The Ninth Circuit, alone among the courts to consider the question, has adopted and applied in this case a pleading standard that demands no factual specificity, but merely the articulation of a theory of loss causation that is not implausible per se. The Ninth Circuit, relying on a decision from the Third Circuit considering loss causation evidence at the summary judgment stage, indicated that "'loss causation becomes most critical at the proof stage.'" App. 17a (citing *McCabe* v. *Ernst & Young, LLP*, 494 F.3d 418, 427 n.4 (3d Cir. 2007)).[6] It ignored *Dura*'s emphasis on the importance of adequate *pleading* of loss causation. *Dura*, 544 U.S. at 347-48. Citing an

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[6] *McCabe* was itself quoting a pre-*Dura* Third Circuit decision. 494 F.3d at 427 n.4. *See EP MedSystems, Inc.* v. *EchoCath, Inc.*, 235 F.3d 865, 884 (3d Cir. 2000). The Third Circuit has not had an opportunity to revisit *EP MedSystems* since *Dura*.

earlier Ninth Circuit ruling, the court below evaluated the complaint only to ensure that it "offers 'sufficient detail to give defendants ample notice of [their] loss causation *theory*, and to give us some assurance that the theory has a basis in fact.'" App. 14a-15a (emphasis added) (quoting *Berson*, 527 F.3d at 989-90). According to the Ninth Circuit, the complaint need only provide enough information to show that the theory of loss causation is "not facially implausible." *Id.* at 17a.

The state of the law is strikingly similar in this context to what it was when the Court granted a writ of certiorari in *Tellabs, Inc.* v. *Makor Issues & Rights, Ltd.*, 127 S. Ct. 2499 (2007), to determine the specificity required to allege the heightened pleading standard for intent under the PSLRA. For the reasons the Court granted certiorari in *Tellabs*, it should grant the petition here.

2. This case provides an excellent vehicle to explore the factual specificity required to plead loss causation adequately in a securities fraud case. The complaint at issue, and found adequate by the Ninth Circuit under its especially lenient standard, implicates both substantive components of *Dura*'s loss causation holding. The Ninth Circuit has required no factual basis to believe that plaintiffs here can prove *either* that the loss occurred after the alleged fraud became generally known to the market, or, even if it had, that plaintiffs have any capacity to isolate the losses attributable to the fraud from other confounding factors.

a. As *Dura* held, "a person who 'misrepresents the financial condition of a corporation in order to sell its stock' becomes liable to a relying purchaser 'for the loss' the purchaser sustains 'when the facts . . . become generally known' and 'as a result' share value

'depreciate[s].'" 544 U.S. at 344 (alteration and omission in original) (quoting *Restatement (Second) of Torts* § 548A, cmt. b, at 107). There is no loss causation where "the purchaser sells the shares quickly *before* the *relevant truth begins to leak out*," because "the misrepresentation will not have led to any loss." *Id.* at 342 (emphasis added). As the Fifth Circuit has read *Dura*, "there is no loss attributable to a misrepresentation unless and until the truth is subsequently revealed and the price of the stock accordingly declines." *United States* v. *Olis*, 429 F.3d 540, 546-48 (5th Cir. 2005).

The Ninth Circuit's "not per se implausible" rule permits a plaintiff to evade entirely pleading any market awareness. The Ninth Circuit's analysis does not require a plaintiff to plead facts showing that the truth *ever* became known to the market. Instead, the rule blesses a complaint that simply asserts that a poor earnings report may have amounted to a disclosure of the consequences of an alleged fraud (here, weakened sales allegedly due to fewer prescriptions) without any factual allegations indicating what the market learned and when and how it understood what it had learned.

When Gilead's stock first dropped, analysts attributed the bad news to the revised estimates of wholesaler inventory stocking, and the initial complaints did the same. Only after their original theory of fraud failed did respondents allege that the October 28 earnings report amounted to a disclosure to the market about the scope of off-label marketing via declining prescriptions. But this characterization of events was nothing more than the lawyers' speculative recharacterization of events. Their new theory of loss causation was unaccompanied by any specific factual allegations that, if proved, would

establish that the market understood the report as the lawyers for respondents now imagine it could have. It is clear that under the standards of other courts, the pleading tactic employed by respondents here would have failed.

The disclosures to the market in *Tricontinental* concerned accounting irregularities in a company's 1998 and 1999 financial statements and the company's subsequent bankruptcy. The plaintiffs complained about the 1997 financial statements, and alleged a facially plausible theory: "the 1997 fraud was part of an on-going scheme to overrepresent revenue and . . . the 1998 audit relied in part on historic information." *Tricontinental*, 475 F.3d at 842. The Seventh Circuit held that *Dura* requires more direct allegations of market awareness of the truth: a plaintiff must "specify" that a loss was caused when the truth "'became generally known,'" and the plaintiff "has not identified any statements by [the company or its auditor] that made 'generally known' any problems or irregularities in the 1997 audited financial statement." *Id.* at 843 (quoting *Dura*, 544 U.S. at 344, 345).

The Fifth Circuit, in *Catogas*, rejected a chain of causation by which a stock drop on the news that a company faced potential delisting of its stock was connected to misrepresentations about its stock option accounting. The plaintiffs argued that an internal investigation into the accounting had caused the company to file its annual report late, which had exposed it to delisting. *Catogas*, 292 F. App'x at 314-15. The Fifth Circuit read *Dura* to require that "[p]laintiffs must allege . . . that the market reacted negatively to a corrective disclosure, which revealed the falsity of [the defendant's] previous representations." *Id.* at 314. The claim in *Catogas* failed because

"the only information . . . *not* previously disclosed to the market—*potential delistment*—did nothing to reveal previous misstatements with respect to [the company's] stock-option accounting." *Id.* at 315.

The Fourth Circuit, in *Teachers*, even though not applying Rule 9(b) standards, dismissed a pleading under its (and the Second Circuit's) heightened Rule 8 standard—loss causation must be pled "with sufficient specificity to enable the court to evaluate whether the necessary causal link exists"—that likewise cannot be squared with the permissive approach to pleading taken by the Ninth Circuit. In *Teachers*, the complaint premised loss causation on the theory that an executive's lawsuit alleging ongoing schemes to inflate revenue revealed the fraudulent nature of the company's prior accounting. *Teachers*, 477 F.3d at 186-87. The court rejected the plaintiffs' invitation to speculate about the plausible causes of the market's negative reaction to the lawsuit:

> While plaintiffs respond that "the market *would have construed* [the executive's] allegations . . . broadly since [the company] had previously denied that it engaged in round-tripping," the problem remains that [the executive's] 2003 complaint is devoid of even general allegations of round-tripping.
>
> . . . .
>
> To allege loss causation in this case, plaintiffs would have to allege that the market reacted to new facts disclosed [on the date of the lawsuit] that revealed [the company's] previous representations to have been fraudulent.

Id. at 187 (emphasis added).

Other cases have likewise required a factual basis to believe that the market understood an alleged disclosure to reveal what securities fraud plaintiffs assert it revealed. See also *Joffee* v. *Lehman Bros.*, 209 F. App'x 80, 81 (2d Cir. 2006); *Glaser* v. *Enzo Biochem, Inc.*, 464 F.3d 474, 479 (4th Cir. 2006), *cert. denied*, 549 U.S. 1304 (2007); *DE&J Ltd. P'ship* v. *Conaway*, 133 F. App'x 994, 995, 999-1000 (6th Cir. 2005). Without such a factual basis, a securities fraud complaint should be dismissed, according to these decisions. Yet the Ninth Circuit permits a complaint devoid of such factual allegations to survive. The Ninth Circuit's unique leniency, especially in light of the dispute among the circuits regarding whether Rule 9(b) applies, warrants this Court's review.

b. The second part of *Dura*'s loss causation test is even more problematic for respondents and the Ninth Circuit. *Dura* requires respondents to allege facts which provide more than a speculative reason to believe they can isolate the effects of the fraud from other causes of their loss. They have not even tried to do this, and the Ninth Circuit freed them from that obligation. No other court that has considered the question would allow such a complaint to survive a motion to dismiss.

The potentially confounding causes of the stock price drop in October 2003 are obvious. Analyst reports, statements from Gilead officers, and the plaintiffs themselves all attributed the disappointing earnings report to a greater than anticipated wholesaler inventory build in the second quarter and corresponding drawdown in the third quarter. Even if it were true that there had been some decline in Viread demand, and even if it were true that the drop had been caused by disclosure of the FDA Warning Letter, the effects of wholesaler inventory build and

subsequent drawdown did not simply disappear. Yet the Ninth Circuit did not require that respondents allege any facts that suggest they can isolate the effects of the alleged fraud from the myriad other factors *known* to have impacted the stock price in October 2003.[7] Other courts, applying an appropriately more stringent pleading standard, require more.

The Second Circuit, in *Lattanzio*, held that loss causation was not adequately pleaded against auditors of a company that went bankrupt, where the auditors signed off on financial statements that overstated shareholder equity by 65% due in part to a $97 million understatement of liabilities. *Lattanzio*, 476 F.3d at 151-53. The plaintiffs argued that their losses were caused by the company's unexpectedly bad financial condition, but the Second Circuit rejected the claim on the pleadings. The Second Circuit held that the losses plaintiffs sought could not all be attributable to auditors' alleged misstatements, and that the complaint was properly dismissed because the plaintiffs had not "alleged facts that would allow a factfinder to ascribe some rough

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[7] There is good reason, even at this early stage of the litigation, to believe that the impact of factors unrelated to the alleged fraud is substantial. The allegations of fraud went to a systemic weakness in the market of Gilead's then-leading product. If that were the principal or even a substantial reason for the drop in the stock price, the price would not recover quickly. Yet publicly available sources that are appropriate to consider on a motion to dismiss reveal plainly that within a month, the entire loss had been recovered, and that Gilead actually reached its originally projected total Viread sales for 2003. The Ninth Circuit simply ignored these facts.

proportion of the whole loss to [the auditor's] misstatements." *Id.* at 158.[8]

In *Schaaf*, the plaintiff bondholders sued two lenders who allegedly concealed defaults in "debt-to-worth" loan covenants by the issuing company (United). The lenders eventually declared defaults and stopped lending to United, causing loss to United's bondholders. In the case of one lender (RFC), the plaintiffs alleged that it stopped lending after sending notice that United violated those very same debt-to-worth covenants. But given the passage of months between the notice and RFC's refusal to lend, the Eighth Circuit held that "plaintiffs have not adequately alleged how RFC's 1998 letter, or the breach it recognized, *caused* RFC to stop lending money to United." *Schaaf*, 517 F.3d at 552-53. As the Eighth Circuit observed,

> [t]he passage of time in this case is particularly significant, because the complaint alleges that United suffered from poor home sales in the fall of 1998, which caused slowdowns in production and closings, which in turn reduced the availability of cash to United. The *Dura* court noted that such a change in economic circumstances could defeat a plaintiff's attempt to prove loss causation and give added significance to the passage of time.

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[8] *See also ATSI Commc'ns, Inc.* v. *Shaar Fund, Ltd.*, 493 F.3d 87, 106-07 (2d Cir. 2007); *Leykin* v. *AT&T Corp.*, 216 F. App'x 14, 16 (2d Cir. 2007), *aff'g* 423 F. Supp. 2d 229, 246 (S.D.N.Y. 2006). Here the risk of wholesaler inventory stocking was always a fully-disclosed risk. And, as of the date of the disclosure of the FDA Warning Letter, so was off-label marketing. Thus, under the Second Circuit's *Lattanzio* standard, neither risk was "concealed" by Gilead prior to the October 28 press release.

Id. at 553. In at least the Second and Eighth Circuits, the failure of the complaint to account for known confounding factors running through an attenuated chain of alleged causation is fatal; in the Ninth Circuit it is not even a wound.

The Ninth Circuit's "not per se implausible" pleading standard permits plaintiffs to substitute a chain of speculative hypotheses for facts that give reason to believe plaintiffs can actually prove loss causation under *Dura*. This Court in recent years has frequently dismissed pleadings that rested on overly attenuated chains of causation. See *Stoneridge Inv. Partners, LLC* v. *Scientific-Atlanta, Inc.*, 128 S. Ct. 761, 769-70 (2008); *Anza* v. *Ideal Steel Supply Corp.*, 547 U.S. 451, 458-60 (2006); *Holmes* v. *SIPC*, 503 U.S. 258, 269-74 (1992). The Ninth Circuit's not "per se implausible" standard for pleading loss causation opens the door to precisely the kinds of "intricate, uncertain inquiries" this Court warned against in *Anza*. 547 U.S. at 459-60. Accordingly, this case provides an excellent opportunity for this Court to articulate a pleading standard for loss causation that comports with the Court's recent pleading and securities law cases.

c. The Ninth Circuit stated that it did not need to decide whether to apply Rule 9(b). App. 14a. The fact that the Ninth Circuit believed its analysis was consistent with Rule 9(b) standards provides still further reason for this Court to review this decision.

The Ninth Circuit's "not per se implausible" standard is wholly irreconcilable with Rule 9(b), which requires pleading of "the who, what, when, where, and how: the first paragraph of any newspaper story." *DiLeo* v. *Ernst & Young*, 901 F.2d 624, 627 (7th Cir. 1990) (Easterbrook, J.); see also *Lachmund* v. *ADM Investor Servs., Inc.*, 191 F.3d

777, 784 (7th Cir. 1999) (pleading of misrepresentations under Rule 9(b) "must be specific with respect to the time, place, and content of the alleged false representations, the method by which the misrepresentations were communicated, and the identities of the parties to those misrepresentations"). Under Rule 9(b), "a plaintiff claiming fraud or mistake must do more pre-complaint investigation to assure that the claim is responsible and supported, rather than defamatory and extortionate." *Borsellino* v. *Goldman Sachs Group, Inc.*, 477 F.3d 502, 507 (7th Cir. 2007) (quotation and alteration omitted). A plaintiff "cannot sufficiently plead fraud by simply providing a method for the defendant to discover the underlying details. If [the plaintiff] has access to the details necessary to make these allegations, it must plead them and not just tell the defendants to go find them." *See ATSI Commc'ns, Inc.* v. *Shaar Fund, Ltd.*, 493 F.3d 87, 106-07 (2d Cir. 2007).

"Rule 9(b) has four purposes: First, the rule ensures that the defendant has sufficient information to formulate a defense by putting it on notice of the conduct complained of . . . . Second, Rule 9(b) exists to protect defendants from frivolous suits. A third reason for the rule is to eliminate fraud actions in which all the facts are learned after discovery. Finally, Rule 9(b) protects defendants from harm to their goodwill and reputation." *United States ex rel. Harrison* v. *Westinghouse Savannah River Co.*, 352 F.3d 908, 921 (4th Cir. 2003) (internal quotations omitted). The Ninth Circuit's "not per se implausible" standard only addresses the first of these purposes, which is what Rule 8 historically achieved, and completely disregards the rest.

The discovery that would be required to establish respondents' theory of causation in this case serves to

illustrate why Rule 9(b) should apply with particular force to theories of proximate causation that do not rest on the market directly learning the circumstances constituting the fraud. A typical "corrective disclosure" case is premised upon information that is, by definition, *public knowledge* at the time a complaint is filed. Thus, as *Dura* anticipated, it will "not prove burdensome for a plaintiff who has suffered an economic loss to provide a defendant with some indication of the loss and the causal connection that the plaintiff has in mind." *Dura*, 544 U.S. at 347.

Here, by contrast, respondents admit they will need to conduct discovery of Gilead's internal sales records to seek to substantiate their allegations. Respondents will also need extensive discovery of third-party wholesalers and doctors to fish for support for their theory that the independent actions of those parties were caused by the FDA Warning Letter rather than some other cause, support that is thus far absent from their pleadings. Not only will this be expensive and burdensome discovery in pursuit of facts that there is no basis in the complaint to believe respondents can or will uncover, but it will place the incendiary charge of fraud before Gilead's customers, thus inflicting the kind of reputational damage against which Rule 9(b) protects.

The shifting theories of fraud and loss causation that respondents have pled throughout this litigation reflect the opposite of what Rule 9(b) is supposed to ensure. Respondents asserted fraud quickly (about two weeks after the October 28 report and market response thereto) and have been developing theories to support their rash assertion ever since. Rule 9(b) is supposed to ensure that *prior* to filing a complaint, the plaintiff has done sufficient factual digging to warrant a public attack on the defendant's reputation

and imposing on the defendant the cost of defending the serious charge being asserted. The Ninth Circuit's casual dismissal of the meaningful pleading burdens of Rule 9(b) make this an especially appropriate case in which to determine whether Rule 9(b) or some other form of heightened pleading applies here.

Further, the theory of loss causation upon which respondents settled reflects a particularly pernicious sort of backward-looking, sue-first-develop-a-story-later approach. Respondents initially ignored the FDA Warning Letter, which was perfectly sensible because analysts and investors did too. There was and is no reason to believe the market was concerned about the Warning Letter's effect on demand for Viread or Gilead's business in general. Only after their initial effort to plead a claim failed did they seize upon the Warning Letter as a causal hook. If courts are to permit such regulatory notices to serve as the after-the-fact hooks upon which plaintiffs can, on the basis of no facts, hang their theory of loss causation and force a company to endure lengthy and costly securities fraud litigation, then regulated industries—including drug companies, insurance companies, power companies, banks, and many others—will find themselves especially exposed to suits whenever a stock drop occurs within some undefined period of months after a regulatory notice is issued. This Court has made clear that the securities laws do not permit such costs to be so readily imposed on regulated entities.

3. The pleading standard for loss causation is an important issue for this Court to resolve. Securities litigation has remained active and will likely only gain further steam in the face of a highly volatile

market.[9] This Court has repeatedly noted that Congress passed the PSLRA "to curb frivolous, lawyer-driven litigation" resulting in "'nuisance filings, targeting of deep-pocket defendants, vexatious discovery requests and manipulation by class-action lawyers.'" *Tellabs*, 127 S. Ct. at 2508-09 (quoting *Merrill Lynch, Pierce, Fenner & Smith Inc.* v. *Dabit*, 547 U.S. 71, 81 (2006)). In the PSLRA, Congress armed courts with the tools necessary to end speculative securities litigation at an early stage, before it could cause harm to a publicly traded company and our financial markets in general. See *Id.* at 2508 ("Setting a uniform pleading standard for § 10(b) actions was among Congress' objectives when it enacted the PSLRA."). Loss causation is often a contested and potentially dispositive element of a securities fraud claim. If an unduly lenient pleading standard applies to loss causation allegations, as the Ninth Circuit held here, then much of the good Congress sought to accomplish with the PSLRA will be lost. Given the ability of plaintiffs' lawyers to find

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[9] One 2006 study found that the average U.S. listed company stands a 10% chance of facing a securities class action in any given five-year period. *See Interim Report of the Committee on Capital Markets Regulation* 74 (Nov. 30, 2006), *available at* http://www.capmktsreg.org/pdfs/11.30Committee_Interim_ReportREV2.pdf. And the incidence of such suits is rising: 217 federal securities class actions were filed from July 2007 through June 2008, a 72% increase over the levels from 2005-07. *See* Cornerstone Research, *Securities Class Action Filings, 2008 Mid-Year Assessment* 2 (2008), *available at* http://securities.cornerstone.com/pdfs/2008%20Mid-Year%20Assessment.pdf. Indeed, 9.2% of the companies in the S&P 500 index, accounting for 17% of the market value of that index, were named as defendants in securities class actions filed in 2008 alone. *See* Cornerstone Research, *Securities Class Action Filings, 2008: A Year in Review* 7 (2008), *available at* http://securities.cornerstone.com/pdfs/YIR2008.pdf.

putative plaintiffs anywhere in the United States, the existence of a single outlying Circuit promises to promote forum shopping and expose corporations that sell securities in national markets to the burdens of litigation that would not exist in any other Circuit. Only this Court can remedy that problem.

CONCLUSION

For the foregoing reasons, the petition for writ of certiorari should be granted.

Respectfully submitted,

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February 6, 2009

APPENDIX

APPENDIX A

UNITED STATES COURT OF APPEALS
NINTH CIRCUIT

No. 06-16185

In re GILEAD SCIENCES SECURITIES LITIGATION.

RICK HARTMAN, on behalf of himself and all others similarly situated; TRENT ST. CLARE; TERRY JOHNSON,
Plaintiffs-Appellants,

v.

GILEAD SCIENCES, INC.; JOHN C. MARTIN; JOHN F. MILLIGAN; MARK L. PERRY; NORBERT W. BISCHOFBERGER; ANTHONY CARRACIOLO; WILLIAM LEE,
Defendants-Appellees.

Argued and Submitted Dec. 6, 2007
Filed Aug. 11, 2008

Appeal from the United States District Court
for the Northern District of California;
Martin J. Jenkins, District Judge, Presiding.
D.C. No. CV-03-04999-MJJ.

Before: ALEX KOZINSKI, *Chief Judge*, HAWKINS, and ROBERT E. COWEN,* *Circuit Judges*.

MICHAEL DALY HAWKINS, *Circuit Judge*:

A group of individual investors brought this securities fraud action on behalf of themselves and

* The Honorable Robert E. Cowen, Senior United States Circuit Judge for the Third Circuit, sitting by designation.

a proposed class comprising all individuals (collectively, the "Investors") who purchased Gilead Sciences, Inc.'s ("Gilead") publicly traded securities between July 14, 2003, and October 28, 2003 ("class period"). They allege that Gilead misled the investing public by representing that demand for its most popular product was strong without disclosing that unlawful marketing was the cause of that strength.

The district court dismissed under Rule 12(b)(6) of Civil Procedure, holding that the Investors failed to sufficiently allege loss causation. We have jurisdiction under 28 U.S.C. § 1291, and we reverse.

FACTS AND PROCEDURAL HISTORY

I. The Complaint's Allegations

The Investors' Fourth Amended Complaint ("complaint") alleges violations of sections 10(b) and 20(a) of the Securities Exchange Act of 1934, 15 U.S.C. §§ 78j(b), 78t(a), and SEC Rule 10b-5, 17 C.F.R. § 240.10b-5. The complaint names as defendants Gilead and some of its top officers ("Officers").

Taking its allegations as true, the complaint tells the following story about Gilead and its marketing practices.[1]

Gilead is a biopharmaceutical company that specializes in developing and marketing treatments for life-threatening diseases. One of the company's

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[1] We recount only those facts necessary for understanding the loss causation issue. The complaint, which spans over seventy pages, offers much greater detail. Because we disagree with the district court on the issue, we frequently quote the complaint to demonstrate that the Investors did in fact explicate the causal logic underlying their theory.

commercial products is Viread, an antiretroviral agent used in combination with other drugs to treat HIV.

Gilead's fortunes, as reflected in its stock price, depended heavily on Viread's commercial success. Sales of Viread amounted to about 65% of Gilead's total revenues at all relevant times of this action. "Wall Street analysts looked to sales of Viread, Gilead's most important and most promoted drug, to gauge whether the Company's business was on track and growing. If Gilead failed to publicly report healthy, growing Viread sales, its stock price would be greatly diminished."

Although Gilead had a clear incentive to aggressively promote Viread, it was required to comply with federal law, including the Food and Drug Administration's ("FDA") marketing regulations. Generally, those regulations prohibit the marketing of drugs for non-FDA-approved uses, commonly referred to as "off-label" uses. "For example, it would be considered off-label for a company to market a FDA-approved HIV/AIDS drug as also being effective for fighting Hepatitis B infection . . . if such use of the drug had not been reviewed and approved by the FDA and included in the" drug's FDA-approved package labeling. While physicians are free to prescribe drugs for off-label uses,[2] they rely on the FDA-approved prescribing information to determine which drugs can be used safely and

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[2] *See* 21 U.S.C. § 396; *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350-51 & n. 5, 121 S.Ct. 1012, 148 L.Ed.2d 854 (2001) (explaining that "the FDA is charged with the difficult task of regulating the marketing and distribution of medical devices without intruding upon decisions statutorily committed to the discretion of health care professionals").

effectively by patients with specific health problems. The FDA approved Viread for use in approximately 40% of the available HIV patient pool. Repeatedly violating the FDA's off-label marketing regulations in an effort to have Viread prescribed to some of the remaining 60% of available HIV patients, Gilead and its officers:

> implemented a scheme to promote and market Viread with off-label, false, and misleading statements in violation of the Federal Food, Drug, and Cosmetic Act. In order to gain market share, artificially increase perceived demand, and increase sales, Gilead officers, executives, and clinical personnel, with the express knowledge and approval of the [Officers], routinely and consistently provided Gilead's sales and marketing team with off-label information and encouraged, expected, and directed them to use it to sell Viread. . . .

Gilead's management began preparing Gilead's sales staff for off-label marketing as early as September 2001, one month before Viread received FDA approval. Management continued to encourage off-label marketing throughout 2002 and the first half of 2003.

These training efforts produced their intended effect. According to two confidential witnesses who served as Gilead salespeople,[3] Viread "off-label marketing took three forms: (1) marketing to HIV

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[3] One of the confidential witnesses served as "a member of Gilead's Field Marketing Advisory Committee, a select committee of Gilead sales and marketing staff that periodically met to discuss theories and strategies for marketing and selling Viread."

patients co-infected with Hepatitis B; (2) marketing Viread as a first-line or initial therapy for HIV infection; and (3) marketing against Viread's safety profile." Ultimately, 75% to 95% of Viread sales resulted from off-label marketing efforts.

The company and its Officers emphasized to the public that they carefully complied with federal and state regulations, when in fact they knew that they were acting unlawfully by aggressively marketing Viread for off-label uses.

The first sign of trouble came on March 14, 2002, when the FDA sent an "Untitled Letter" to Gilead that accused the company of understating the risks of Viread—a form of improper off-label marketing. The letter ordered Gilead to "immediately cease" this practice. On March 21, 2002, per the FDA's request, Gilead sent a reply that acknowledged receipt of the FDA's letter and agreed to immediately stop off-label marketing. This was not done. In fact, Gilead's off-label marketing increased, either at the Officers' direction or with their knowledge and tacit encouragement.

By June 2003, Gilead's off-label marketing put it in the position to raise Viread's price. Consistent with standard industry practice, Gilead informed national drug wholesalers of this plan in advance of the price increase. The wholesalers (there are the three major ones that purchase approximately ninety percent of drug manufacturers' drugs) typically stockpile drugs in advance of price increases so that they can resell at a higher price to retailers after the increase takes effect.

Because Gilead had "illegally inflated sales and artificially inflated demand for Viread, the major

drug wholesalers stockpiled mass quantities of Viread in advance of the June 2003 price increase. This wholesaler stockpiling would not have occurred but for the off-label marketing and the resulting creation of an artificially increased demand for Viread." The stockpiling furthered Gilead's fraudulent scheme by confirming "the impression that Viread was in high demand and that Gilead's financial and operational results were strong."

On July 14, 2003, Gilead issued a press release announcing that it anticipated its second quarter financial results would exceed analysts' expectations, and explaining that the company's success "was driven primarily by strong sales growth of Viread. . . . Increasing Viread sales reflect broader prescribing patterns in all commercial markets, as well as increases in U.S. wholesaler inventory levels in the second quarter in anticipation of a Viread price increase."

These statements were materially false and misleading because Gilead and its Officers' "marketing and promotional activities for Viread were not in compliance with FDA approved guidelines, violated federal laws, and created serious public health and safety implications for Viread users." Gilead's promotional scheme was designed to, and did, create the impression that demand for Viread was strong. This campaign was misleading, however, because it was unlawful off-label marketing that was driving prescription volume[4]—and Gilead had already been ordered to cease such marketing.

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[4] The Investors concluded that between $86.7 million and $109.82 million of Viread's $115.6 million in domestic sales during the second quarter of 2003 could be attributed to off-label marketing.

While securities analysts, for the most part, reacted favorably to the July 14, 2003, press release, Gilead and its Officers felt the need to respond to some analysts' concern that second quarter revenues were primarily attributable to the wholesaler stockpiling, and not a result of strong demand. On the same day that the press release was issued, a Gilead spokeswoman, acting with the knowledge and approval of Gilead and its officers, told Bloomberg News that "[t]he main reason for the jump in Viread sales is an increase in prescriptions, not inventory stocking." This statement was misleading. It created the impression that demand for Viread was strong, which it was, but for reasons that were not well-understood by the public. Omitting the role of off-label marketing in a press release highlighting the drug's success made a true statement (that demand was strong) also a misleading one.

Gilead's financial news had a marked effect on its stock price. On July 14, the price of Gilead shares closed at $67.25, up $7.97 from the previous day's closing price of $59.28 per share. This 13.4% increase represented a near-record high.

Some two weeks later, the FDA issued a July 29 Warning Letter[5] that chastised Gilead for statements made by one of its sales representatives at

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[5] The Complaint explains:

> According to the FDA's website and the FDA's Regulatory Procedures Manual, warning letters such as this are written communications from the [FDA] to a company notifying the company that the [FDA] considers one or more promotional pieces or practices to be illegal. . . . A warning letter is much more serious than an untitled letter.

the 15th National HIV/AIDS Update Conference in March and April of 2003. The letter stated that the employee "made oral statements that minimized the risk information and broadened the indication for Viread." It reminded Gilead of the Untitled Letter, expressed the "significant public health and safety concerns raised by these repetitive promotional activities," and ordered Gilead to make corrective disclosure. Gilead made such disclosure to the conference attendees on November 7, 2003.

On August 7, 2003, the FDA made public its Warning Letter. Gilead's shareholders and the investing public did not find it very significant, though, because they failed to appreciate the extent of Gilead's off-label marketing, and thus could not foresee the letter's impact on Viread's sales.

The public's underestimation of Viread's troubles was reflected in Gilead's share price. Notwithstanding the public revelation of the letter, shares closed at higher prices than they opened on both August 7 and August 8. Indeed, by the end of August, the stock was trading a few dollars higher than it had been at the beginning of the month, without having experienced any significant fluctuations.

Yet, "[u]nbeknownst to investors, the disclosure of the FDA Warning Letter had a detrimental effect on Viread sales. Physicians, now alerted to Gilead's illegal marketing efforts and to the safety problems with Viread, were less eager to prescribe it to their patients." Competitors invoked the letter in efforts to persuade physicians to switch from Viread to their products. In the remaining weeks of August, there was a "marked drop in prescriptions and sales" of Viread. Although the Investors lack precise sales figures, a Morgan Stanley analyst report

shows that Viread prescriptions experienced a "sharp drop" in August 2003, followed by "flattened growth" for the remainder of the third quarter. The prescriptions would have suffered further decline were it not for certain side-effects that made it dangerous for some patients to discontinue using the drug.

The wholesalers observed the initial drop in sales and prescriptions of Viread, and the ensuing slow growth. Because Viread was underperforming relative to the expectations generated by the second quarter reports, the wholesalers drew down much more of their excess inventory than they had originally planned, letting supply of Viread drop to the lowest level in four quarters, and well below the industry average for other drugs.

Although wholesalers recognized Viread's struggles, the public continued to misunderstand the significance of the Warning Letter. Gilead did nothing to correct that misunderstanding. In its Form 10-Q reporting on the 2003 second quarter, issued on August 14, Gilead persisted in emphasizing the increased volume of Viread's second quarter sales without discussing the role of off-label marketing. Although the Form 10-Q did briefly address the Warning Letter, it failed to reveal the activities that gave rise to that letter, or the impact the letter would have on sales of Viread.

The Officers exploited the public's ignorance. In the days between the receipt and public disclosure of the Warning Letter, two of the Officers each sold over $3 million worth of stock. On August 7, the day the FDA disclosed the letter, Gilead's Senior Vice President/Chief Financial Officer sold nearly $700,000 worth of shares. Throughout August,

while the market misapprehended Gilead's impending troubles, the Officers continued to sell off substantial numbers of shares. This activity was "unusual and suspicious" because this was the first month in which all of the Officers sold stock. More to the point, this was proof that the Officers acted with knowledge or with deliberate recklessness when they issued materially false and misleading documents and statements that were disseminated to the investing public.

Not until October 28, 2003, did the public finally realize the impact of the off-label marketing and the Warning Letter. After the markets closed that day, Gilead issued a press release detailing third quarter financial results. The public learned that Viread sales fell significantly below expectations because there had been substantially more overstocking by wholesalers than previously reported. Accordingly, third quarter prescriptions were filled by wholesalers' existing inventory, and wholesalers did not reorder Viread at a commensurate level. Market analysts attributed the disappointing sales to "lower end-user demand." That lower end-user demand, as noted, was a direct result of the Warning Letter, which had exposed Gilead's unlawful off-label marketing efforts to physicians.

The market was "stunned" by the third quarter results. Share prices closed at $59.46 on October 28, before the press release was circulated. It may be the case that the market had already begun to slowly incorporate the information regarding Viread's off-label marketing into the share price. But the third-quarter earnings release made the effect of that information inescapably clear. The day after the press release was issued, trading volume

of Gilead shares was up 1,400% from its average daily level. The day opened with Gilead's price per share at $50.69, and closed with a price of $52 per share, a 12% decrease from the previous day's closing price.

Summing it all up,

> At all relevant times, the material misrepresentations . . . directly or proximately caused or were a substantial contributing cause of the damages sustained by [the Investors]. . . . [Gilead and the Officers] made or caused to be made a series of materially false or misleading statements about Gilead's sales, business, product marketing and promotion, prospects, operations and financial results. These material misstatements had the cause and effect of creating in the market an unrealistically positive assessment of Gilead . . . thus causing the Company's publicly traded securities to be overvalued and artificially inflated at all relevant times.

II. The District Court's Decision

The district court dismissed the complaint with prejudice. Based on the Investors' allegations and judicially-noticed documents that had been referenced in the complaint, the court concluded that the Investors had failed to adequately plead loss causation as that requirement was articulated in *Dura Pharmaceuticals, Inc. v. Broudo*, 544 U.S. 336, 125 S.Ct. 1627, 161 L.Ed.2d 577 (2005).

Specifically, the district court found the complaint failed to

> connect the following chain of events . . . : 1) that [Gilead's and the Officers'] alleged failure

> to disclose the off-label marketing scheme caused a material increase in sales; 2) that practitioners materially decreased their demand for Viread due to the publication of the FDA Warning Letter; and most importantly, 3) that the alleged decrease in sales due to the FDA letter proximately caused Gilead's stock to decrease three months later[.]

The district court rested its decision exclusively on loss causation, and did not consider whether the Investors sufficiently alleged falsity or scienter.

DISCUSSION

I. Standards of Review

"We review de novo the district court's dismissal of a complaint for failure to state a claim under Federal Rule of Civil Procedure 12(b)(6). On review, we accept the plaintiffs' allegations as true and construe them in the light most favorable to plaintiffs." *Gompper v. VISX, Inc.*, 298 F.3d 893, 895 (9th Cir.2002) (citation omitted). "The court need not, however, accept as true allegations that contradict matters properly subject to judicial notice or by exhibit. Nor is the court required to accept as true allegations that are merely conclusory, unwarranted deductions of fact, or unreasonable inferences." *Sprewell v. Golden State Warriors*, 266 F.3d 979, 988 (9th Cir.2001) (citation omitted), *amended on other grounds*, 275 F.3d 1187 (9th Cir.2001). The complaint is properly dismissed if it fails to "plead 'enough facts to state a claim to relief that is plausible on its face.'" *Weber v. Dep't of Veterans Affairs*, 521 F.3d 1061, 1065 (9th Cir.2008) (quoting *Bell Atl. Corp. v. Twombly*, --- U.S. ----, 127 S.Ct. 1955, 1974, 167 L.Ed.2d 929 (2007)).

II. Applicable law

Section 10(b) of the Securities Exchange Act of 1934 makes it unlawful "[t]o use or employ, in connection with the purchase or sale of any security . . . any manipulative or deceptive device or contrivance in contravention of such rules and regulations as the Commission may prescribe." 15 U.S.C. § 78j(b). Pursuant to this section, the Securities and Exchange Commission promulgated Rule 10b-5, which makes it unlawful:

> (a) To employ any device, scheme, or artifice to defraud,
>
> (b) To make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading, or
>
> (c) To engage in any act, practice, or course of business which operates or would operate as a fraud or deceit upon any person, in connection with the purchase or sale of any security.

17 C.F.R. § 240.10b-5.

We have identified five basic elements of a Rule 10b-5 claim: "(1) a material misrepresentation or omission of fact, (2) scienter, (3) a connection with the purchase or sale of a security, (4) transaction and loss causation, and (5) economic loss." *In re Daou Sys., Inc.*, 411 F.3d 1006, 1014 (9th Cir.2005) (citing *Dura Pharms.*, 544 U.S. at 341-42, 125 S.Ct. 1627).

Because the district court addressed only loss causation under Rule 10b-5, we will limit our consideration to that issue, "following the general

rule [that] a federal appellate court does not consider an issue not passed upon below." *Miller v. Thane Int'l, Inc.*, 519 F.3d 879, 892 (9th Cir.2008) (alteration in original; internal quotation marks omitted). A plaintiff bears the burden of proving that a defendant's alleged unlawful act "caused the loss for which the plaintiff seeks to recover damages." 15 U.S.C. § 78u-4(b)(4). To establish loss causation, "the plaintiff must demonstrate a causal connection between the deceptive acts that form the basis for the claim of securities fraud and the injury suffered by the plaintiff." *Daou*, 411 F.3d at 1025. The misrepresentation need not be the sole reason for the decline in value of the securities, but it must be a "'substantial cause.'" *Id.* (quoting *Robbins v. Koger Props., Inc.*, 116 F.3d 1441, 1447 n. 5 (11th Cir.1997)).

Rule 9(b) of Civil Procedure provides: "In alleging fraud . . . a party must state with particularity the circumstances constituting fraud. . . ." Gilead and the Officers contend that the Investors' loss causation arguments should be subject to this heightened pleading requirement, although they recognize that the Supreme Court has not decided the issue. *See Dura Pharms.*, 544 U.S. at 346, 125 S.Ct. 1627. The Investors argue that Rule 8(a)(2)'s "short and plain statement" requirement should control loss causation pleading.

We need not resolve this issue today. Rule 9(b) imposes the heightened requirement so that the fraud-action defendant "can prepare an adequate answer from the allegations." *Odom v. Microsoft Corp.*, 486 F.3d 541, 553 (9th Cir.2007) (internal quotation marks omitted). As we explain below, the Investors' complaint offers "sufficient detail to give

defendants ample notice of [their] loss causation theory, and to give us some assurance that the theory has a basis in fact." *Berson v. Applied Signal Tech., Inc.*, 527 F.3d 982, 989-90 (9th Cir. 2008). Therefore, under either Rule 8 or Rule 9, the Investors have sufficiently pleaded loss causation.

III. The Sufficiency of the Complaint

The district court identified *Dura Pharmaceuticals* as the authority that doomed the Investors' complaint. *Dura* featured plaintiffs who alleged that they "paid artificially inflated prices" for Dura's securities and "suffered damages thereby." *Dura*, 544 U.S. at 339-40, 125 S.Ct. 1627 (alterations, emphasis, and quotation marks omitted). The court below had held that loss causation was established merely by demonstrating that share prices on the date of purchase were inflated. *Broudo v. Dura Pharms., Inc.*, 339 F.3d 933, 938 (9th Cir.2003).

The Supreme Court reversed, and held that an inflated purchase price alone is not enough to establish loss causation. *Dura*, 544 U.S. at 342, 125 S.Ct. 1627. More is required of plaintiffs—particular allegations as to "what the relevant economic loss might be," and "what the causal connection might be" between the fraud alleged and the economic losses actually suffered. *Id.* at 347, 125 S.Ct. 1627.

The complaint in this case is meaningfully different from that in *Dura Pharmaceuticals*. The Investors here identify a specific economic loss: the drop in value on October 29, 2003, that followed the October 28 press release. They also allege that this loss was caused by Gilead's misrepresentations.

They provide abundant details of Gilead's off-label marketing, and they assert that this led to higher demand for Viread, which in turn inflated Gilead's stock price.[6] As summarized in the complaint's introduction,

> [T]he market was not told that off-label marketing was the cornerstone of demand. This mistaken impression of demand led to, among other things, wholesaler overstocking in reaction to an anticipated price increase. When the truth about [Gilead's and the Officers'] off-label marketing was disclosed, however, [they] could no longer maintain the sales growth levels that investors had come to expect, and Gilead's stock price dropped accordingly.

Assuming, then, that the Investors' theory is sound and that they can prove all that they allege, the district court erred by holding that *Dura Pharmaceuticals* compelled dismissal of this action.

The dismissal order below, though, suggests that the district court was unwilling to make these assumptions. The district court found that the complaint contained "too many logical and factual gaps."

Based on our own review, we find the complaint sufficiently alleges a causal relationship between (1) the increase in sales resulting from the off-label marketing, (2) the Warning Letter's effect on Viread

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[6] The complaint includes one concrete example of how Gilead's stock price was directly inflated by Viread's sales performance: the 13.4% rise in share value triggered by Gilead's positive statements about demand for Viread on July 14, 2003, the first day of the class period.

orders, and (3) the Warning Letter's effect on Gilead's stock price.

Perhaps what truly motivated the dismissal was the district court's incredulity. The court expressly identified two allegations it was unwilling to accept. First, it could not make "the unreasonable inference that a public revelation on August 8 *caused* a price drop *three months later* on October 28." Order Granting Defs.' Mot. to Dismiss at 11. Second, with respect to the Warning Letter's impact on Viread sales, the court found "a slowing increase in demand, alone, too speculative to adequately demonstrate loss causation." *Id.* at 12 n. 10.

As an initial matter, we note that a district court ruling on a motion to dismiss is not sitting as a trier of fact. It is true that the court need not accept as true conclusory allegations, nor make unwarranted deductions or unreasonable inferences. *Sprewell*, 266 F.3d at 988. But so long as the plaintiff alleges facts to support a theory that is not facially implausible, the court's skepticism is best reserved for later stages of the proceedings when the plaintiff's case can be rejected on evidentiary grounds. "[A] well-pleaded complaint may proceed even if it strikes a savvy judge that actual proof of those facts is improbable, and that a recovery is very remote and unlikely." *Bell Atl. Corp. v. Twombly*, --- U.S. ---, 127 S.Ct. 1955, 1965, 167 L.Ed.2d 929 (2007) (internal quotation marks omitted).

There is no exception to this rule for the element of loss causation. The Third Circuit has stated that "loss causation becomes most critical at the proof stage," and has cited scholarly authority stating that it is normally inappropriate to rule on loss causation at the pleading stage. *McCabe v. Ernst &*

Young, LLP, 494 F.3d 418, 427 n. 4 (3rd Cir.2007) (internal quotation marks omitted). Similarly, the Second Circuit has held that loss causation "is a matter of proof at trial and not to be decided on a Rule 12(b)(6) motion to dismiss." *Emergent Capital Inv. Mgmt., LLC. v. Stonepath Group, Inc.*, 343 F.3d 189, 197 (2d Cir.2003). *But see Lentell v. Merrill Lynch & Co.*, 396 F.3d 161, 172-77 (2d Cir.2005) (failure to plead any facts supporting loss causation warranted 12(b)(6) dismissal of complaint).

We agree. So long as the complaint alleges facts that, if taken as true, plausibly establish loss causation, a Rule 12(b)(6) dismissal is inappropriate. This is not "a probability requirement . . . it simply calls for enough fact to raise a reasonable expectation that discovery will reveal evidence of" loss causation. *Bell Atl.*, 127 S.Ct. at 1965.

The district court's concern about the elapse of time between the public issuance of the Warning Letter and the drop in price recalls our holding in *No. 84 Employer-Teamster Joint Council Pension Trust Fund v. America West Holding Corp.*, 320 F.3d 920 (9th Cir.2003) (internal quotation marks omitted). There, a Rule 10b-5 defendant argued that its alleged misrepresentations were per se immaterial because the injurious drop in stock price took place more than one and a half months after the market learned the truth about the misrepresentations. *Id.* at 934. We rejected "a bright-line rule requiring an immediate market reaction" because "[t]he market is subject to distortions that prevent the ideal of a free and open public market from occurring." *Id.* (internal quotation marks omitted). Instead, we held that courts must engage

in a "fact-specific inquiry." *Id.* (internal quotation marks omitted).

We believe that *America West's* discussion of materiality applies with equal force to the loss causation requirement. A limited temporal gap between the time a misrepresentation is publicly revealed and the subsequent decline in stock value does not render a plaintiff's theory of loss causation per se implausible.

Our review of the Investors' complaint convinces us that the October drop in stock price was plausibly caused by the Warning Letter. Importantly, the drop occurred immediately after Gilead disclosed less-than-expected revenues resulting from the reduction in wholesalers' Viread inventories, which analysts ascribed to lower end-user demand. That lower end-user demand, in turn, is expressly alleged to have been caused by the Warning Letter. In this light, the market did react immediately to the corrective disclosure—the October 28 press release. The Warning Letter, which discussed only two instances of off-label marketing, would not necessarily trigger a market reaction because it did not contain enough information to significantly undermine Gilead's July 2003 pronouncements concerning demand for Viread. It is not unreasonable that physicians—the targets of the off-label marketing—would respond to the Warning Letter while the public failed to appreciate its significance.

The district court also erroneously concluded that a slowing increase in demand is too speculative to establish loss causation. Had the Investors alleged that the Warning Letter eliminated all sales resulting from off-label marketing, it would be very unlikely that demand would continue to increase,

since the complaint asserts that 75% to 95% of sales were caused by off-label marketing. But they do not allege that, and we see no reason why the court cannot proceed to the evidentiary stages to determine the extent of the Warning Letter's impact on the growth of demand for Viread.

The complaint specifically alleges that physicians were less eager to prescribe Viread, and competitors used the Warning Letter to lure Viread customers to other drugs. This is "enough fact to raise a reasonable expectation that discovery will reveal evidence"—or the lack thereof—of the Warning Letter's effect on demand. *Bell Atl.*, 127 S.Ct. at 1965.

CONCLUSION

For the foregoing reasons, the district court improperly granted Gilead's and the Officers' Rule 12(b)(6) motion. The Investors have sufficiently alleged loss causation and economic loss. We leave it to the district court to determine whether they have sufficiently alleged the other elements of their claims.

REVERSED and *REMANDED*.

APPENDIX B

UNITED STATES DISTRICT COURT,
N.D. California.

In re GILEAD SCIENCES SECURITIES LITIGATION.

This Document Relates To All Actions.

Nos. C03-4999 MJJ, C03-5391 MJJ,
C04-0100 MJJ, C03-5088 MJJ,
C03-5592 MJJ, C03-5113 MJJ,
C03-5805 MJJ.

May 12, 2006.

ORDER *GRANTING* DEFENDANTS' 12(b)(6)
MOTION TO DISMISS

MARTIN J. JENKINS, District Judge.

INTRODUCTION

Before the Court is Gilead Sciences, Inc. ("Gilead"), John C. Martin, John F. Milligan, Mark L. Perry, Norbert W. Bischofberger, Anthony Carrociolo and William A. Lee's ("Defendants") Motion to Dismiss a federal securities fraud action brought against them by a class consisting of all purchasers of Gilead stock between July 14, 2003 and October 28, 2003.[1] Defendants seek an order dismissing the Fourth Amended Class Action Complaint ("FAC") with prejudice under

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[1] Docket No. 140, filed on December 22, 2005.

the heightened pleading requirements of the Private Securities Litigation Reform Act of 1995 ("PSLRA") and pursuant to Federal Rules of Civil Procedure 12(b)(6) and 9(b). For the following reasons, the Court GRANTS Defendants' motion with prejudice.

BACKGROUND

A. Factual History

The FAC is brought on behalf of a class consisting of all persons who purchased or otherwise acquired Gilead stock between July 14, 2003 and October 28, 2003 (the "Class Period"). The allegations in the FAC relate to Gilead's announcement in July 2003 of its financial results for the second quarter of 2003, and the impact its premier product, Viread, had on those results. Viread is a antiretroviral drug used to treat HIV/AIDS that Gilead introduced in 2001. On July 14, 2003, the first day of the class period, Gilead issued a press release entitled "Gilead Sciences Expects Second Quarter 2003 Financial Results Will Exceed Expectations," and stating, "[t]he increase in revenue was driven primarily by strong sales growth of Viread." The press release went on to say that Viread sales increased due to "broader prescribing patterns . . . as well as increases in U.S. wholesaler inventory in the second quarter." On the same day, *Bloomberg News* identified Gilead spokeswoman Amy Flood as stating that "[t]he main reason for the jump in Viread sales is an increase in prescriptions, not inventory stocking."

Two weeks later, on July 31, 2003, Gilead issued a press release containing its final results for the second quarter. Gilead announced that it had net revenues of $230.7 million for the second quarter, of which $167 million related to Viread. Gilead went on:

> Viread sales growth was primarily driven by higher prescription volume, a significant increase in U.S. wholesaler inventories and a favorable European currency environment compared to the same quarter last year. Gilead estimates that increased stocking by U.S. wholesalers accounted for $25-30 million in Viread sales in the second quarter.

The press release contained warnings regarding the forward-looking statements and stated that the statements were "subject to certain risks and uncertainties, which could cause actual results to differ materially." Statements made during Gilead's earnings call of that same date, as well as on its Form 10-Q filed August 14, 2003, contained similar warnings.

Also on July 31, 2003, Gilead held a conference call with analysts and other investors regarding its financial results. During the call, an officer of Gilead stated:

> Of significant note, we believe that a substantial inventory build occurred in U.S. distributor channel during the second quarter as wholesalers anticipated the Viread price increase announced on June 27th. Though difficult to determine the exact figure for this inventory build, we estimate that wholesaler inventories increased by $25 to $30 million during the quarter. . . . Based on the U.S. inventory build up seen in the second quarter, we anticipate Viread sales for the third quarter will be at or below the sales level recognized this second quarter. We expect these inventories to be drawn down to more normal levels during this quarter.

According to the FAC, market analysts—including Morgan Stanley, Prudential, and Bear Stearns—continued to predict strong demand for Viread in the third quarter of 2003 despite the inventory overstock.

On August 14, 2003, Gilead filed its Form 10-Q for the second quarter of 2003. This form confirmed the previously announced financial results. The Form 10-Q also discussed the inventory build-up: "We estimate that this higher stocking resulted in $25.0 to $30.0 million of additional sales during the second quarter, which may adversely impact sales in the third quarter as wholesalers return to more normal inventory levels and buying patterns." The Form 10-Q also disclosed the existence of a July 29, 2003 letter issued by the FDA warning Gilead about certain aspects of its promotional practices of Viread.[2]

In its October 28, 2003 Press Release, Gilead announced its financial results for the third quarter of 2003, Gilead announced net revenues of $194.1 million, and sales of Viread of $115.4 million. At that time, Gilead stated: "After reviewing NDC prescription trends, IMS inventory data and actual Viread sales, Gilead estimates there was approximately $33 to $37 million of inventory reduction by U.S. pharmaceutical wholesalers during the third quarter of 2003 following an equivalent inventory build during the second quarter of 2003." The next day, Gilead's stock dropped $7.46 per share from $59.46 per share to close at $52 per share. Approximately one month later, on December 2, 2003, Gilead's stock price had recovered the entire drop experienced on October 29 and closed at $59.83 per share.

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[2] Gilead initially made the FDA letter public on August 7, 2003.

Plaintiffs allege that for the period of at least September 2001 through, and subsequent to, the class period, Gilead engaged in the off-label marketing of Viread. Off-label marketing refers to the use for marketing purposes of information such as the result of clinical studies and other material on the uses of and the efficacy of an FDA-approved product that has not been approved by the FDA for inclusion in the product's package labeling. Pursuant to FDA guidelines, pharmaceutical manufacturers such as Gilead may only promote an FDA-approved drug consistent with the contents of its FDA-approved package labeling. Plaintiffs assert that the off-label marketing took three forms: 1) marketing to HIV patients co-infected with Hepatitis B virus ("HBV"); 2) marketing Viread as a first-line or initial therapy for HIV infection; and 3) marketing against Viread's safety profile.

Plaintiffs allege that Gilead's off-label marketing activities began as early as September 2001 at Gilead's national sales meeting in Miami. There, sales and marketing employees allegedly were given information regarding Gilead's submission of Viread clinical data and information to the FDA and, with a "wink and a nod," were instructed to use this information to sell Viread even though Viread had yet to be approved by the FDA. The FDA approved Viread in October 2001.[3] Later, employees allegedly were instructed, "overtly and covertly," at numerous regional and national sales meetings by Gilead executives to use off-label information to aggressively promote and sell Viread.[4] At these meetings, employees

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[3] From October 2001 to August 2003, Viread's market share increased steadily from zero to nearly 20 percent.

[4] The FAC states that Plaintiffs' confidential witnesses (CW1 and CW2) attended various meetings at which Gilead's sales

allegedly would be provided off-label information such as updates on clinical trials of Viread on large group meetings and then told in subsequent smaller meetings to use this information to sell Viread. Defendants Martin, Perry, Lee, Milligan, and Bischofberger allegedly attended one or more of these regional and national sales meetings.

According to the FAC, Gilead received an Untitled FDA Letter on March 14, 2002, advising the company that its representatives had made false and misleading oral promotional statements at the December 2001 Interscience Conference on Antimicrobial Agents and Chemotherapy conference. According to the Untitled FDA Letter, Gilead falsely and misleadingly promoted Viread by stating that it contained "no toxicities," was "extremely safe," and was "extremely well-tolerated," despite the fact that its boxed warning and Package Labeling advised to the contrary. The Untitled FDA Letter further ordered Gilead to "immediately cease making such violative statements," and required Gilead to submit a written response describing its intent and plans to comply with the FDA's directives. Plaintiffs allege that the false statements were made by Defendant Martin and it was company-wide knowledge that Martin was the cause of the Untitled FDA Letter.

On March 21, 2002, Gilead responded saying that it was "commit[ted] to ensure that future violative statements are not made in the promotion of Viread." However, sixteen months later, on July 29, 2003, the

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and marketing team received specific instructions to market Viread off-label. According to CW1, 85% to 95% of his Viread sales were a result of off-label marketing. Plaintiffs also allege that 85% to 90% of CW2's Viread sales were a result of off-label marketing.

FDA issued a second letter ("FDA Warning Letter") notifying Gilead that it considered certain oral representations made by a Gilead representative at a promotion booth during a conference call in April 2003 to be improper. This conference took place during Gilead's second fiscal quarter of 2003, just prior to Defendants' first class period announcement of outstanding Viread sales and financial results which exceeded market expectations.

This second FDA letter became public on August 7, 2003. According to the FAC, investors did not attribute much significance to the letter. (FAC at ¶ 191.) In response to the FDA letter on November 7, 2003, defendant Martin wrote a correction letter to the conference attendees.

Plaintiffs allege that Defendants provided so many off-label instructional materials and were so forceful in promoting off-label use, that 75% to 95% of Viread sales were attributable to off-label promotion. According to the FAC, this accounted for between $86.7 million and $109.82 million of Gilead's second quarter 2003 domestic Viread sales. (FAC at ¶ 150.) Plaintiffs allege that Defendants maintained this misleading image of Viread for a long enough period for the stock price to become inflated and for Defendants to sell their shares before the FDA made their second letter to Gilead public.

B. Procedural History

On January 25, 2005, the Court dismissed Plaintiffs' Consolidated Amended Complaint ("CAC") with leave to amend, finding that Plaintiffs failed to establish the requisite connection between Gilead's off-label marketing activities and the allegedly false 2003 second quarter reports. Plaintiffs filed the Third

Consolidated Amended Class Action Complaint ("TAC") on March 11, 2005.[5] On October 11, 2005 the Court dismissed Plaintiffs' TAC with leave to amend ("Order"). Once again the Court found Plaintiffs' pleadings deficient. Although the Court voiced its concerns as to whether Plaintiffs adequately demonstrated that the off-label marketing scheme "materially" affected Gilead's sales or stock price, it did not reach that issue on the merits. Instead the Court found Plaintiffs' pleadings deficient because they failed to allege loss causation in light of *Dura Pharmaceuticals, Inc. v. Broudo*, 125 S.Ct. 1627 (2005),[6] and *In re Daou Systems, Inc.*, 411 F.3d 1006 (9th Cir.2005).[7] The Court held "in light of *Dura*, it is evident that Plaintiffs have not adequately alleged proximate causation and economic loss with respect to Gilead's alleged off-label marketing scheme." (Order at 12:21-23.) The Court ruled that "Plaintiffs [did] not allege that a price drop immediately accompanied the disclosure of the FDA [W]arning [L]etter, and hence the Court is left to speculate as to what portion of the eventual loss, if any, should be attributed to the disclosure or whether the loss was caused by

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[5] Plaintiffs filed their Second Consolidated Amended Class Action Complaint on February 25, 2005 (Docket No. 99), which they amended shortly thereafter with the TAC.

[6] The Supreme Court decided *Dura* after the Court dismissed the CAC. *Dura* held that in order to demonstrate loss causation, plaintiffs must establish an actual "causal connection" between the defendants' material misrepresentation and the economic loss suffered. *Dura*, 125 S.Ct. at 1631-33.

[7] The Ninth Circuit decided *Daou* after the Court dismissed the CAC as well. There, the Ninth Circuit held that a plaintiff sufficiently pleads "loss causation" by alleging that there was a steep drop in defendants' stock price upon revelation of previously undisclosed facts. *Daou*, 411 F.3d at 1026.

other factors." (Order at 12:23-26.) Plaintiffs filed the FAC on December 2, 2005 in response to the Order.

JUDICIAL NOTICE

In addition to the Motion to Dismiss the FAC, Defendants have filed a Request for Judicial Notice, and ask the Court to notice a number of documents. Federal Rule of Evidence 201 allows a court to take judicial notice of a fact "not subject to reasonable dispute in that it is . . . capable of accurate and ready determination by resort to sources whose accuracy can[ ]not reasonably be questioned." Plaintiffs do not object to the Court's taking judicial notice of the requested documents. The Court finds taking judicial notice of those documents and all other requested documents appropriate here. *Branch v. Tunnell*, 14 F.3d 449, 454 (9th Cir.1994), *cert. denied*, 512 U.S. 1219 (1997); *In re Calpine Corp. Sec. Lit.*, 288 F.Supp.2d 1054, 1076 (N.D.Cal.2003). Accordingly, the Court takes notice of all such documents.[8]

LEGAL STANDARDS

A. Rule 12(b)(6)

A court may dismiss a complaint pursuant to Federal Rule of Civil Procedure 12(b)(6) for either lack of a cognizable legal theory or the pleading of insufficient facts under an adequate theory. *Robertson v. Dean Witter Reynolds, Inc.*, 749 F.2d 530, 533-34 (9th Cir.1984). When deciding upon a motion to dismiss for failure to state a claim upon which relief can be granted pursuant to Rule 12(b)(6), a court must take

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[8] In its order dismissing the CAC the Court judicially noticed several of the documents for which Defendants ask for judicial notice in this motion to dismiss. (Amended Order Granting Defendants' 12(b)(6) Motion To Dismiss, 5:20-21.)

all of the material allegations in the plaintiff's complaint as true, and construe them in the light most favorable to the plaintiff. *Parks School of Business, Inc. v. Symington*, 51 F.3d 1480, 1484 (9th Cir.1995). Moreover, a complaint should not be dismissed unless the plaintiff could prove no set of facts in support of his claim that would entitle that plaintiff to relief. *Id.*

In the context of a motion to dismiss, review is limited to the contents of the complaint. *Allarcom Pay Television, Ltd. v. General Instrument Corp.*, 69 F.3d 381, 385 (9th Cir.1995). When matters outside the pleading are presented to and accepted by the court, the motion to dismiss is converted into one for summary judgment. Where such a conversion takes place, all parties must be given an opportunity to present all material made pertinent to such a motion by Rule 56. *In re Pacific Gateway Exchange, Inc. Sec. Lit.*, 169 F.Supp.2d 1160, 1164 (N.D.Cal.2001); *see also* Fed.R.Civ.P. 12(b). However, matters properly presented to the court, such as those attached to the complaint and incorporated within its allegations, may be considered as part of the motion to dismiss. *See Hal Roach Studies, Inc. v. Richard Feiner & Co.*, 896 F.2d 1542, 1555 n 19 (9th Cir.1989).

Where a plaintiff fails to attach to the complaint documents referred to in it, and upon which the complaint is premised, a defendant may attach to the motion to dismiss such documents in order to show that they do not support the plaintiff's claim. *See Pacific Gateway Exchange*, 169 F.Supp.2d at 1164; *Branch*, 14 F.3d at 454. Thus, the district court may consider the full texts of documents that the complaint only quotes in part. *See In re Stac Electronics Sec. Lit.*, 89 F.3d 1399, 1405 n. 4 (1996), *cert. denied*, 520 U.S. 1103 (1997). This rule precludes a plaintiff "from sur-

viving a Rule 12(b)(6) motion by deliberately omitting references to documents upon which [the] claims are based." *Parrino v. FHP, Inc.*, 146 F.3d 699, 706 (9th Cir.1998).

B. Section 10(b) And Rule 10b-5

Section 10(b) of the Securities Exchange Act ("Act") provides, in part, that it is unlawful "to use or employ in connection with the purchase or sale of any security registered on a national securities exchange or any security not so registered, any manipulative or deceptive device or contrivance in contravention of such rules and regulations as the [SEC] may prescribe." 15 U.S.C. § 78j(b).

Rule 10b-5 makes it unlawful for any person to use interstate commerce

> (a) to employ any device, scheme, or artifice to defraud;
>
> (b) to make any untrue statement of material fact or to omit to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading; or
>
> (c) to engage in any act, practice, or course of business which operates or would operate as a fraud or deceit upon any person, in connection with the purchase or sale of any security.

17 C.F.R. § 240.10b-5.

To be actionable under section 10(b) and Rule 10b-5, a plaintiff must allege 1) a misrepresentation or omission; 2) of material fact; 3) made with scienter; 4) on which the plaintiff justifiably relied; 5) that proximately caused the alleged loss. *See Binder v. Gillespie*, 184 F.3d 1059, 1063 (9th Cir.1999). Addi-

tionally, as in all actions alleging fraud, plaintiffs must state with particularity the circumstances constituting fraud. Fed.R.Civ.P. 9(b).

C. Section 20(a)

Section 20(a) of the Act provides derivative liability for those who control others found to be primarily liable under the Act. *In re Ramp Networks, Inc. Sec. Lit.*, 201 F.Supp.2d 1051, 1063 (N.D.Cal.2002). Where a plaintiff asserts a section 20(a) claim based on an underlying violation of section 10(b), the pleading requirements for both violations are the same. *Id.*

D. Private Securities Litigation Reform Act

In 1995, Congress enacted the PSLRA to provide "protections to discourage frivolous [securities] litigation." H.R. Conf. Rep. No. 104-469, 104th Conf., 1st Sess. at 32 (1995) (Nov. 28, 1995). The PSLRA strengthened the pleading requirements of Rules 8(a) and 9(b). Actions based on allegations of material misstatements or omissions under the PSLRA must "specify each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and, if an allegation regarding the statement or omission is made on information and belief, the complaint shall state with particularity all facts on which that belief is formed." 15 U.S.C. § 78u-4(b)(1).

The PSLRA also heightened the pleading threshold for causes of action brought under Section 10(b) and Rule 10b-5. Specifically, the PSLRA imposed strict requirements for pleading scienter. A complaint under the PSLRA must "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." 15 U.S.C. § 78u-4(b)(2). The Ninth Circuit, in interpreting the

PSLRA, has held that "a private securities plaintiff proceeding under the [PSLRA] must plead, in great detail, facts that constitute strong circumstantial evidence of deliberately reckless or conscious misconduct." *In re Silicon Graphics, Inc. Sec. Lit.*, 183 F.3d 970, 974 (9th Cir.1999). If the complaint does not satisfy the pleading requirements of the PSLRA, upon motion by the defendant, the court must dismiss the complaint. *See* 15 U.S.C. § 78u-4(b)(1).

ANALYSIS

After the Court dismissed Plaintiffs' TAC for failure to adequately allege loss causation, Plaintiffs amended their complaint on December 2, 2005. Plaintiffs' amendments primarily consist of allegations that market analysts predicted an increase in Gilead's sales despite the overstock of Viread. Again, Plaintiffs rely on three types of allegations to support their Section 10(b) action: 1) Defendants' statements and omissions regarding wholesaler overstocking; 2) the alleged financial impact of the off-label marketing scheme; and 3) the individual Defendants' own stock sales. Defendants move the Court to dismiss the FAC with prejudice pursuant to the PSLRA and Federal Rules of Civil Procedure 9(b) and 12(b)(6), arguing that Plaintiffs fail to adequately plead loss causation, falsity, and scienter.

A. Loss Causation

Allegations of "loss causation" are a necessary element of a § 10(b) claim. *Dura*, 125 S.Ct. at 1631. Merely alleging that a misrepresentation caused an inflated purchase price does not, without more, demonstrate loss causation. *Id.* at 1631-32. It is insufficient for a misrepresentation to "touch upon" an economic loss; a plaintiff must demonstrate an actual

"causal connection" between the defendant's material misrepresentation and the economic loss suffered. *Id.* at 1632. In other words, "to prove loss causation, the plaintiff must demonstrate a causal connection between the deceptive acts that form the basis for the claim of securities fraud and the injury suffered by the plaintiff." *Daou*, 411 F.3d at 1025.

Defendants argue that Plaintiffs still have not established a "causal connection" between the disclosure of the FDA's warning letter (containing the off-label marketing allegations) and the drop in Gilead's stock price. Defendants contend that the additional information provided in the FAC has added little to Plaintiffs' previous complaint, which insufficiently pled loss causation.

In support of their position, Plaintiffs point to the following allegations from the FAC: 1) Defendants' alleged off-label marketing caused increased prescriptions and sales, which caused legitimate demand due to "explosive growth"; 2) Defendants' scheme was followed by the FDA Warning Letter forbidding Gilead from engaging in off-label marketing; and 3) this letter caused a slow down in demand for Viread, which in turn caused a slow down in sales, resulting in a stock price decline. According to Plaintiffs, the resulting slow down in sales and consequential stock decline was "foreseeable and well within the 'zone of risk' concealed by Defendants' [off-label marketing]." (Plaintiffs' Corrected Memorandum of Points and Authorities in Opposition to Motion to Dismiss FAC at 17:17.)

As the Court found in its previous order, Plaintiffs' allegations regarding loss causation are simply too attenuated. Plaintiffs continue to allege that the disclosure of the August 8, 2003 FDA Warning Letter

coupled with the announcement of disappointing sales in the October 28, 2003 Press Release shocked investors and caused the price of Gilead stock to drop.[9] To satisfy the loss-causation requirement, Plaintiffs must allege that the material misrepresentation caused their loss. The fundamental problem with Plaintiffs' allegations is that they require the Court to make the unreasonable inference that a public revelation on August 8 *caused* a price drop *three months later* on October 28. There was no price drop immediately after the August 8 revelation. The new allegations in Plaintiffs' FAC merely reinforce the Court's finding regarding the reasonableness of this inference and do little to meet their loss causation pleading burden.

Several of Plaintiffs' new allegations require the Court to make unwarranted inferences that the FDA Warning Letter was the cause of the lower demand for Viread. Plaintiffs attempt to support these allegations with citations to general conclusions in market analyst reports by Morgan Stanley, Prudential, and Bear Stearns. Neither the new allegations nor the market analyst reports help Plaintiffs' loss causation claim. First, Plaintiffs' assertion that the FDA Warning Letter was the cause of the lower demand for Viread still does not establish a causal connection. Even if the FDA Warning Letter caused practitioners to reduce their Viread supply, Plaintiffs still fail to connect that with the drop in stock price.

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[9] The Court noted in its Order that "this argument is flawed because the record reflects that investors never actually learned the extent of Defendants' off-label marketing scheme." (Order Granting Motion to Dismiss at 12:18-19, Doc. No. 136).

Additionally, the Court finds the market analyst reports problematic because they undermine Plaintiffs' theory that the disclosure led to a decrease in demand. The reports do not predict a decrease in demand at all. Indeed, they suggest that the demand for Viread would continue to grow. (Defendants' Motion to Dismiss FAC at Ex. G.) Further, the reports simply restated what Gilead had already stated in its October 28, 2003 Press Release—that Viread would expect lower end-user demand during the third quarter due to higher than normal inventories entering that quarter. (Defendants' Motion to Dismiss FAC at Ex. G, I.) Thus, the Court finds that the market analyst reports do not shed any new light on the loss causation issue.[10]

Plaintiffs correctly argue that the heightened pleading standard does not apply to allegations that Defendants' misrepresentations caused their loss. *Dura*, 125 S.Ct at 1633-34. However, Plaintiffs reliance on *In re Parmalat Sec. Litigation*, 375 F.Supp.2d 278 (S.D.N.Y.2005), and *Teamsters Local 445 Freight Div. Pension Fund v. Bombardier Inc.*, 2005 U.S. Dist. LEXIS 19506 (S.D.N.Y. Sept 6, 2005), to support the proposition that merely alleging a corrective disclosure followed by a decline in stock price is sufficient to plead loss causation, is misplaced. The Court finds this case distinguishable from *Parmalat* and *Teamsters* as the price drop in those cases occurred soon after the revelation of the misrepresentation.[11]

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[10] Defendants concede the demand for Viread did not increase at the same rate in the third quarter. The Court, however, finds a slowing increase in demand, alone, too speculative to adequately demonstrate loss causation.

[11] The Court has reviewed the other cases to which Plaintiffs cite and finds them equally distinguishable.

Parmalat involved a drop in securities price after disclosure of a fraud that understated Parmalat's debt by virtually $10 billion and overstated the corporation's assets by over $16 billion. *Parmalat*, 375 F.Supp.2d at 282. To support their allegations of securities fraud, the plaintiffs alleged that the company's auditor, Delcitte, issued two financial reports with the understated debts and overstated assets. *Id.* at 307. About eighteen months later, Parmalat was unable to repay its bonds when they became due and publicly disclosed that a $4.9 billion bank account it supposedly held did not exist. *Id.* at 284. This was immediately followed by a drop in stock price. *Id.* at 307. There the district court found the plaintiffs adequately pled loss causation because the "[d]efendants reasonably could have foreseen that Parmalat's inability to service its debt would lead to a financial collapse." *Id.*

Similarly, the plaintiff in *Teamsters* alleged senior management of Bombardier Capital Inc. ("BCI"), a manufactured housing asset-backed company, disregarded the companies' underwriting standards in favor of high-risk loans. *Teamsters*, 2005 U.S. Dist. LEXIS 19506, at *7. BCI did not disclose on its Form 8-K filing or otherwise its actual underwriting practices and thus concealed the high-risk loans. *Id.* at *6. The high-risk loans turned into "bad loans" and resulted in a sharp increase in delinquencies and foreclosure on BCI assets. *Id.* at *8. As a result, BCI's stock certificates suffered a price decrease of 38% in less than three months. *Id.* at *7. There the district court found the plaintiff adequately alleged loss causation:

> Plaintiff has alleged that its loss was caused when a risk that was concealed by the defen-

> dants materialized in a foreseeable chain of events. The Complaint alleges that defendants' misrepresentations regarding rigorous underwriting concealed the fact that the collateral pool contained a substantial number of high risk loans. The concealed risk materialized when the collateral pool experienced high delinquency rates and repossession on a sustained basis. Not surprisingly, BCI's earnings expectations then fell. BCI announced that it would write off the losses, rating agencies downgraded the Certificates, and the value of plaintiff's investment declined. These allegations are sufficient to plead loss causation.

Id. at *57.

The case before the Court, however, is substantially different. Both *Parmalat* and *Teamsters* involved the omission and subsequent disclosure of substantial corporate debt that clearly related to the decline in stock value. A fundamental principle of causation is "that the injury averred must proceed directly from the wrong alleged and must not be attributable to some supervening cause."[12] *Marbury Mgmt., Inc. v. Kohn*, 629 F.2d 705, 716-17 (2d

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[12] There are too many logical and factual gaps in Plaintiffs' allegations to support the conclusion that Defendants' alleged misconduct proximately caused Gilead's stock decrease in October. *Dura*, 125 S.Ct. at 1632. The FAC does not connect the following chain of events, which it must for Plaintiffs to adequately plead loss causation: 1) that Defendants' alleged failure to disclose the off-label marketing scheme caused a material increase in sales; 2) that practitioners materially decreased their demand for Viread due to the publication of the FDA Warning Letter; and most importantly, 3) that the alleged decrease in sales due to the FDA letter proximately caused Gilead's stock to decrease three months later.

Cir.1980) (Meskill, J., dissenting). It is worth reiterating that the FDA letter became public on August 7, 2003, and the loss which that revelation allegedly caused occurred nearly *three months* later on October 29, 2003. Consequently, the Court is left to speculate as to what portion, if any, of that decrease should be attributed to the alleged misconduct and what should be attributed to other market factors. A court need not indulge unwarranted inferences in determining whether a plaintiff has adequately pled a necessary element. *In re Verifone Sec. Lit.*, 11 F.3d 865, 868 (9th Cir.1993). Even viewed in the light most favorable to Plaintiffs,[13] the Court finds that Plaintiffs have not adequately pled, under *Dura*, that the alleged misrepresentation proximately caused their loss.[14] Accordingly, the Court must dismiss the Complaint.[15]

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[13] The Court must consider all reasonable inferences to be drawn from the allegations, "including inferences unfavorable to the plaintiffs." *Gompper v. VISX, Inc.*, 298 F.3d 893, 897 (9th Cir. 2002).

[14] The Court distinguishes this case from *Daou*. In *Daou*, the defendants fraudulently inflated their stock price through accounting methods which violated Generally Accepted Accounting Practices. *Daou*, 411 F.3d at 1012. There, the Ninth Circuit found loss causation because plaintiffs alleged a steep drop in stock price following disclosure of Defendants' "true financial health." *Id.* at 1026. Here, however, Plaintiffs have not adequately connected the disclosure of Gilead's off-label marketing and the drop in stock price in the FAC. Indeed, the evidence Plaintiffs have presented to the Court only supports an inference that the market gave little or no weight to the FDA Warning Letter.

[15] Because Plaintiffs have not adequately alleged loss causation, the Court need not consider whether Plaintiffs have adequately alleged falsity or scienter.

B. Rule 20(a) Liability

Section 20(a) of the Securities Exchange Act provides derivative liability for those who control others found to be primarily liable under the Act. *In re Ramp Networks, Inc. Sec. Lit.*, 201 F.Supp.2d at 1063. Where a plaintiff asserts a Section 20(a) claim based on an underlying violation of Section 10(b), the pleading requirements for both violations are the same. *Id.* Because Plaintiffs have failed to adequately plead the underlying 10b-5 violation, the Section 20(a) claims must be dismissed against the individual Defendants as well.

C. Dismissal With Prejudice

A court considers five factors in determining whether to dismiss a complaint with prejudice: 1) bad faith, 2) undue delay, 3) prejudice to the opposing party, 4) futility of the amendment, and 5) whether plaintiff has previously amended his complaint. *Allen v. City of Beverly Hills*, 911 F.2d 367, 373 (9th Cir. 1990). A court's "discretion to deny leave to amend is particularly broad where plaintiff has previously amended the complaint." *Id.* (quoting *Ascon Properties, Inc. v. Mobil Oil Co.*, 866 F.2d 1149, 1160 (9th Cir.1989)).

Plaintiffs have filed four amended complaints, and this is the third complaint that the Court has dismissed. The Court found that Plaintiffs failed to allege with the requisite detail, falsity and scienter, when it dismissed Plaintiffs' CAC with leave to amend. The Court dismissed the TAC for failure to adequately plead loss causation, but it reiterated its concerns regarding the sufficiency of Plaintiffs' falsity and scienter allegations. Because *Daou* was decided after Plaintiffs filed their TAC, the Court again

granted leave to amend with respect to the issue of loss causation. Yet Plaintiffs still have not adequately alleged loss causation after having had another opportunity to do so. Since Plaintiffs have failed to remedy the deficiencies of their allegations in each amended version, the Court finds that further amendment is futile. Accordingly, the Court DISMISSES the Complaint *with prejudice*.

CONCLUSION

After consideration of the FAC in light of *Dura* and the requirements of Federal Rule of Civil Procedure 12(b)(6), the Court GRANTS Defendants' 12(b)(6) Motion to Dismiss the FAC with prejudice.[16] The Clerk of the Court is directed to close this case.

IT IS SO ORDERED.

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[16] Docket No. 140, filed December 22, 2005.

APPENDIX C

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF
CALIFORNIA

No. C 03-4999 MJJ

In re GILEAD SCIENCES SECURITIES LITIGATION

This Document Relates To: ALL ACTIONS

ORDER *GRANTING* DEFENDANTS' 12(b)(6)
MOTION TO DISMISS

INTRODUCTION

Before the Court is Gilead Sciences, Inc. ("Gilead"), John C. Martin, John F. Milligan, Mark L. Perry, Norbert W. Bischofberger, Anthony Carrociolo and William A. Lee's ("Defendants") Motion to Dismiss a federal securities fraud action brought against them by a class consisting of all purchasers of Gilead stock between July 14, 2003 and October 28, 2003. Defendants seek an Order dismissing the Third Amended Class Action Complaint ("TAC") with prejudice under the heightened pleading requirements of the Private Securities Litigation Reform Act of 1995 ("PSLRA") and pursuant to Federal Rules of Civil Procedure 12(b)(6) and 9(b). For the following reasons, Defendants' motion is GRANTED with leave to amend.

BACKGROUND

A. Factual History

The TAC is brought on behalf of a class consisting of all persons who purchased or otherwise acquired Gilead stock between July 14, 2003 and October 28, 2003. The allegations in the TAC relate to Gilead's announcement in July 2003 of its financial results for the second quarter of 2003, and the impact its premier product, Viread, had on those results. Viread is a groundbreaking antiretroviral drug used to treat HIV/AIDS that was introduced in 2001, On July 14, 2003, the first day of the class period, Gilead issued a press release entitled "Gilead Sciences Expects Second Quarter 2003 Financial Results Will Exceed Expectations," and stating, "[t]he increase in revenue was driven primarily by strong sales growth of Viread." The press release went on to say that Viread sales increased due to "broader prescribing patterns. . . as well as increases in U.S. wholesaler inventory levels in the second quarter." On the same day, *Bloomberg News* identified Gilead spokeswoman Amy Flood as stating that "[t]he main reason for the jump in Viread sales is an increase in prescriptions, not inventory stocking."

Two weeks later, on July 31, 2003, Gilead issued a press release containing its final results for the second quarter. Gilead announced that it had net revenues of $230.7 million for the quarter, of which $167 million related to Viread. Gilead went on:

> Viread sales growth was primarily driven by higher prescription volume, a significant increase in U.S. wholesaler inventories and a favorable European currency environment compared to the same quarter last year. Gilead estimates that

> increased stocking by U.S. wholesalers accounted for $25-30 million in Viread sales in the second quarter.

The press release contained warnings regarding the forward-looking statements and stated that the statements were "subject to certain risks and uncertainties, which could cause actual results to differ materially." Statements made during Gilead's earnings call of that same date, as well as on its Form 10-Q filed August 14, 2003, contained similar warnings.

Also on July 31, 2003, Gilead held a conference call with analysts and other investors regarding its financial results. During the call, an officer of Gilead stated:

> Of significant note, we believe that a substantial inventory build occurred in U.S. distributor channel during the second quarter as wholesalers anticipated the Viread price increase announced on June 27th. Though difficult to determine the exact figure for this inventory build, we estimate that wholesaler inventories increased by $25 to $30 million during the quarter . . . . Based on the U.S. inventory build up seen in the second quarter, we anticipate Viread sales for the third quarter will be at or below the sales level recognized this second quarter. We expect these inventories to be drawn down to more normal levels during this quarter.

On August 14, 2003, Gilead filed its Form 10-Q for the second quarter of 2003. This form confirmed the previously announced financial results. The Form 10-Q also discussed the inventory build-up: "We estimate that this higher stocking resulted in $25.0 to $30.0 million of additional sales during the second

quarter, which may adversely impact sales in the third quarter as wholesalers return to more normal inventory levels and buying patterns." The form 10-Q also disclosed the existence of a July 29, 2003 letter issued by the FDA warning Gilead about certain aspects of its promotional practices of Viread.[1]

On October 28, 2003, Gilead announced its financial results for the third quarter of 2003. Gilead announced net revenues of $194.1 million, and sales of Viread of $115.4 million. At that time, Gilead stated: "After reviewing NDC prescription trends, IMS inventory data and actual Viread sales, Gilead estimates there was approximately $33 to $37 million of inventory reduction by U.S. pharmaceutical wholesalers during the third quarter of 2003 following an equivalent inventory build during the second quarter of 2003." The next day, Gilead's stock dropped $7.46 per share from $59.46 per share to close at $52 per share. Approximately one month later, on December 2, 2003, Gilead's stock price had recovered the entire drop experienced on October 29 and closed at $59.83 per share.

Plaintiffs allege that for the period of at least September 2001 through, and subsequent to, the class period, Gilead engaged in the off-label marketing of Viread. Off-label marketing refers to the use for marketing purposes of information such as the result of clinical studies and other materials on the uses of and the efficacy of an FDA-approved product that has not been approved by the FDA for inclusion in the product's package labeling. Pursuant to FDA guidelines, pharmaceutical manufacturers such as Gilead

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[1] Gilead initially made the FDA letter public on August 7, 2003.

may only promote an FDA-approved drug consistent with the contents of its FDA-approved package labeling. Plaintiffs assert that the off-label marketing took three forms: 1) marketing to HIV patients co-infected with Hepatitis B virus ("HBV"); 2) marketing Viread as a first-line or initial therapy for HIV infection, and 3) marketing against Viread's safety profile.

Plaintiffs allege that Gilead's off-label marketing activities began as early as September 2001 at Gilead's national sales meeting in Miami. There, sales and marketing employees allegedly were given information regarding Gilead's submission of Viread clinical data and information to the FDA and, with a "wink and a nod," were instructed to use this information to sell Viread even though Viread had yet to be approved by the FDA. The FDA approved Viread in October 2001. Later, employees allegedly were instructed at numerous regional end national sales meetings by Gilead executives "overtly and covertly," to use off-label information to aggressively promote and sell Viread.[2] At these meetings, employees allegedly would be provided off-label information such as updates on clinical trials of Viread in large group meetings and then told in subsequent smaller meetings to use this information to sell Viread. Defendants Martin, Perry, Lee, Milligan, and Bischofberger allegedly attended one or more of these regional and national sales meetings.

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[2] The TAC states that Plaintiffs' confidential witnesses (CW1 and CW2) attended various meetings at which Gilead's sales and marketing team received specific instructions to market Viread off-label. According to CW1, 85% to 95% of his Viread sales were a result of off-label marketing. Plaintiffs also allege that 85% to 90% of CW2's Viread sales were a result of off-label marketing.

According to the TAC, Gilead received an Untitled FDA Letter on March 14, 2002, advising the company that its representatives had made false and misleading oral promotional statements at the December 2001 Interscience Conference on Antimicrobial Agents and Chemotherapy conference. According to the Untitled FDA Letter, Gilead falsely and misleadingly promoted Viread by stating that it contained "no toxicities," was "extremely safe," and was "extremely well tolerated," despite the fact that its boxed warning and Package Labeling advised to the contrary. The Untitled FDA Letter further ordered Gilead to "immediately cease making such violative statements," and required Gilead to submit a written response describing its intent and plans to comply with the FDA's directives. Plaintiffs allege that the false statements were made by Defendant Martin and it was company-wide knowledge that Martin was the cause of the Untitled FDA Letter.

On March 21, 2002, Gilead responded stating that it was "commit[ted] to ensure that future violative statements are not made in the promotion of Viread." However, sixteen months later, on July 29, 2003, the FDA issued a second letter notifying Gilead that it considered certain oral representations made by a Gilead representative at a promotional booth during a conference in April 2003 to be improper. This conference took place during Gilead's second fiscal quarter of 2003, just prior to Defendants' first class period announcement of outstanding Viread sales and financial results which exceeded market expectations. In response to and in compliance with this letter, on November 7, 2003, defendant Martin wrote a correction letter to the conference's attendees.

Plaintiffs allege that Defendants provided so much off-label material and were so forceful in instructing off-label information that 75% to 95% of Viread sales arose from off-label promotion. According to the TAC, Gilead's second quarter 2003 domestic Viread sales were overstated by approximately $95 million due to off-label marketing.

B. Procedural History

On January 25, 2005, the Court dismissed Plaintiffs' Consolidated Amended Complaint ("CAC") with leave to amend ("the Order"). The Court found that Plaintiffs failed to "establish a connection between the company's off-label marketing activities and the 2003 second quarter reports that Plaintiffs allege were false and misleading." (Order at 13:17-19.) The Court ruled that to establish such a connection, "Plaintiffs must allege that Gilead's off-label marketing scheme was a 'material fact' that needed to be disclosed to investors along with the 2003 second quarter sales reports." (Order at 13:19-21.) The Court also found that "Plaintiffs have not alleged any sales of Viread during the second quarter of 2003 were the result of improper off-label marketing activities." (Order at 13:22-23.) The Court noted that "Plaintiffs must allege facts that show a relationship between the off-label marketing of Viread, related sales of Viread, and the manner in which those sales affected Gilead's 2003 second quarter financial reports." (Order at 14:6-8.) Plaintiffs filed the TAC on March 11, 2005 in response to the Court's directives in the Order.

LEGAL STANDARDS

A. Rule 12(b)(6)

A court may dismiss a complaint pursuant to Federal Rule of Civil Procedure 12(b)(6) for either lack of

a cognizable legal theory or the pleading of insufficient facts under an adequate theory *Robertson v. Dean Witter Reynolds, Inc.*, 749 F.2d 530, 533-34 (9th Cir. 1984). When deciding upon a motion to dismiss for failure to state a claim upon which relief can be granted pursuant to FRCP 12(b)(6), a court must take all of the material allegations in plaintiff's complaint as true, and construe them in the light most favorable to plaintiff. *Parks School of Business, Inc. v. Symington*, 51 F.3d 1480, 1484 (9th Cir. 1995). Moreover, a complaint should not be dismissed unless a plaintiff could prove no set of facts in support of his claim that would entitle him to relief. *Id.*

In the context of a motion to dismiss, review is limited to the contents in the complaint. *Allarcom Pay Television, Ltd. v. General Instrument Corp.*, 69 F.3d 381, 385 (9th Cir. 1995). When matters outside the pleading are presented to and accepted by the court, the motion to dismiss is converted into one for summary judgment. Where such a conversion takes place, all parties must be given an opportunity to present all material made pertinent to such a motion by Rule 56. *In re Pacific Gateway Exchange, Inc. Sec. Lit.*, 169 F. Supp. 2d 1160, 1164 (N.D. Cal. 2001); *see also* Fed. R. Civ. P. 12(b), However, matters properly presented to the court, such as those attached to the complaint and incorporated within its allegations, may be considered as part of the motion to dismiss. *See Hal Roach Studios, Inc. v. Richard Feiner & Co.*, 896 F.2d 1542, 1555 n.19 (9th Cir. 1989).

Where a plaintiff fails to attach to the complaint documents referred to in it, and upon which the complaint is premised, a defendant may attach to the motion to dismiss such documents in order to show that they do not support plaintiff's claim. *See Pacific*

Gateway Exchange, 169 F. Supp. 2d at 1164; *Branch v. Tunnel*, 14 F.3d 449, 44 [sic] (9th Cir. 1994), *cert. denied*, 512 U.S. 1219 (1997). Thus, the district court may consider the full texts of documents that the complaint only quotes in part. *See In re Slay Electronics Sec. Lit.*, 89 F.3d 1399, 1405 n.4 (1996), *cert denied*, 520 U.S. 1103 (1997). This rule precludes plaintiffs "from surviving a Rule 12(b)(6) motion by deliberately omitting references to documents upon which their claims are based." *Parrino v. FHP, Inc.*, 146 F.3d 699, 705 (9th Cir. 1998).

B. Section 10(b) and Rule 10b-5

Section 10(b) of the Securities Exchange Act provides, in part, that it is unlawful "to use or employ in connection with the purchase or sale of any security registered on a national securities exchange or any security not so registered, any manipulative or deceptive device or contrivance in contravention of such rules and regulations as the [SEC] may prescribe." 15 U.S.C. § 78j(b).

Rule 10b-5 makes it unlawful for any person to use interstate commerce

> (a) To employ any device, scheme, or artifice to defraud.
>
> (b) To make any untrue statement of material fact or to omit to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading, or
>
> (c) To engage in any act, practice, or course of business which operates or would operate as a fraud or deceit upon any person, in connection with the purchase or sale of any security.

17 C.F.R. § 240.10b-5

To be actionable under section 10(b) and Rule 10b-5, a plaintiff must allege (1) a misrepresentation or omission; (2) of material fact; (3) made with scienter; (4) on which the plaintiff justifiably relied; (5) that proximately caused the alleged loss. *See Binder v. Gillespie*, 184 F.3d 1059, 1063 (9th Cir. 1999). Additionally, as in all actions alleging fraud, plaintiffs must state with particularity the circumstances constituting fraud. Fed. R. Civ. P. 9(b).

C. Section 20(a)

Section 20(a) of the Securities Exchange Act ("Exchange Act") provides derivative liability for those who control others found to be primarily liable under the Act. *In re Ramp Networks, Inc. Sec. Lit.*, 201 F. Supp. 2d 1051, 1063 (N.D. Cal. 2002). Where a plaintiff asserts a section 20(a) claim based on an underlying violation of section 10(b), the pleading requirements for both violations are the same. *Id.*

D. Private Securities Litigation Reform Act

In 1995, Congress enacted the PSLRA to provide "protections to discourage frivolous [securities] litigation." H.R. Conf. Rep, No 104-369, 104th Cong., 1st Sess. at 32 (1995)) [sic] (Nov. 28, 1995). The PSLRA strengthened the pleading requirements of Rules 8(a) and 9(b). Actions based on allegations of material misstatements or omissions under the PSLRA must "specify each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and, if an allegation regarding the statement or omission is made on information and belief, the complaint shall state with particularity all facts on which that belief is formed." 15 U.S.C. §78u-4(b)(1).

The PSLRA also heightened the pleading threshold for causes of action brought under Section 10(b) and Rule 10b-5. Specifically, the PSLRA imposed strict requirements for pleading scienter. A complaint under the PSLRA must "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." 15 U.S.C. § 78u-4(b)(2). The Ninth Circuit, in interpreting the PSLRA, has held that "a private securities plaintiff proceeding under the [PSLRA] must plead, in great detail, facts that constitute strong circumstantial evidence of deliberately reckless or conscious misconduct." *In re Silicon Graphics Inc.*, 183 F.3d 970, 974 (9th Cir. 1999). If the complaint does not satisfy the pleading requirements of the PSLRA, upon motion by the defendant, the court, must dismiss the complaint. *See* 15 U.S.C. §78u-4(b)(1).

ANALYSIS

After the Court dismissed Plantiffs' CAC, Plaintiffs filed the TAC on March 11, 2005. The TAC alleges new facts, upon which Plaintiffs now primarily rely. Plaintiffs once again rely upon three theories to support their section 10(b) action: 1) Defendants' statements regarding wholesaler overstocking; 2) the financial impact of the off label marketing scheme; and 3) Defendants' stock sales.[3]

Defendants move the Court to dismiss the TAC with prejudice pursuant to the PSLRA and Federal Rules of Civil Procedure 9(b), and 12(b)(6) on several

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[3] As Plaintiffs have added no new allegations regarding wholesaler overstocking or stock sales, the Court need not address these allegations again. Thus, the Court will focus only upon the allegations involving the alleged off-label marketing scheme.

grounds. Defendants argue that: 1) Plaintiffs fail to adequately allege that Defendants illegally marketed Viread and that material illegal sales resulted from any such marketing; 2) Plaintiffs fail to allege fraud as to the wholesaler inventory estimate; and 3) Plaintiffs fail to adequately allege the element of loss causation.

A. Falsity and Scienter

To avoid having their action dismissed, Plaintiffs must "plead with particularity either the alleged misleading statements or scienter[.]" *In re Fritz Cos. Sec. Litig.*, 282 F. Supp. 2d 1105, 1112 (N.D. Cal 2003). The Ninth Circuit has articulated the rule as follows:

> Because falsity and scienter in private securities fraud cases are generally strongly inferred from the same set of facts, we have incorporated the dual pleading requirements of 15 U.S.C. §§ 78u-4(b)(1) and (b)(2) into a single inquiry. In considering whether a private securities fraud complaint can survive dismissal under Rule 12(b)(6), we must determine whether particular facts in the complaint, taken as a whole, raise a strong inference that defendants intentionally or deliberate recklessness made false or misleading statements to investors. Where pleadings are not sufficiently particularized or where, taken as a whole, they do not raise a "strong inference" that misleading statements were knowingly or deliberate recklessness made to investors, a private securities fraud complaint is properly dismissed under Rule 12(b)(6).

Ronconi v. Larkin, 253 F.3d 423, 429 (9th Cir. 2001) (citations and internal quotation marks omitted).

As the Court found in its previous Order, Plaintiffs have adequately alleged that Defendants engaged in an illegal off-label marketing scheme.[4] (Order at 13:14-16.) When the allegations of CW1 and CW2 are considered in light of the FDA's letters to Gilead, it becomes apparent that Plaintiffs have alleged sufficient facts to raise a strong inference that Defendants had knowledge of the company's off-label marketing scheme.

However, the Court previously found that Plaintiffs failed to establish a connection between the Defendants' off-label marketing activities and the 2003 second quarter reports that Plaintiffs allege were false and misleading.[5] In order to remedy that deficiency, the TAC sheds further light upon the extent and impact of the alleged off-label marketing scheme. Specifically, the TAC relies upon the testimony of CW1 and CW2. According to CW1, 75% to 95% of all Viread sales in the United States were the result of off-label marketing. CW1 also alleges that 85% to 95% of his or her $3 million in Viread sales arose from off-label promotion. Similarly, the TAC states that approximately 85% to 90% of CW2's $25 to $35 million in Viread sales were a result of off-label mar-

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[4] Defendants disagree with this ruling, and contend that "the specific marketing identified in the TAC was fully consistent with Viread's label and thus was completely proper." (Defendants' Motion to Dismiss TAC at 16:28-17:1.) The Court is unpersuaded. While the parties dispute the proper interpretation of the FDA's approval of Viread and Viread Package Labeling, the Court finds that this is a purely factual dispute, and hence it is not susceptible to resolution on a Rule 12(b)(6) motion.

[5] In other words, Plaintiffs must allege that Gilead's off-label marketing scheme was a "material fact" that needed to be disclosed to investors along with the 2003 second quarter sales reports. *See* 15 U.S.C § 78u-4(b)(1)(B).

keting. As a result of off-label marketing, Plaintiffs conclude that Gilead's second quarter 2003 domestic Viread sales of $115.6 million were overstated by approximately $95.95 million. Plaintiffs also conclude that Gilead's third quarter 2003 domestic sales of $59.4 million were overstated by approximately $49.3 million.

Additionally, the TAC details the amount of Viread allegedly sold off-label. For example, according to the TAC, HIV patients co-infected with Hepatitis B initially began using Viread in the third quarter of 2002. At that time, only 55% of co-infected patients were allegedly using Viread. By the third quarter of 2003, 72.7% of co-infected patients surveyed were allegedly using Viread. Plaintiffs allege similar facts regarding the pervasiveness of patients using Viread as a first-line therapy. According to the TAC, Viread had an 11.2% market share as a first-line antiretroviral drug in the fourth quarter of 2001 (TAC at ¶161.) However, by the fourth quarter of 2003, Defendants had allegedly increased this market share to 27.45%. (TAC at ¶161.)

In order to connect these sales increases to Defendants' off-label marketing scheme, Plaintiffs allege that several doctors prescribed Viread for off-label purposes and received unsolicited off-label data from Defendants. For example, Plaintiffs allege that an AIDS-specialist treating between 2,000 and 2,500 AIDS patients prescribed Viread off-label and received unsolicited off-label data from Gilead, (TAC at ¶153.) Plaintiffs also allege that two infectious disease specialists in the Southeast United States both began to receive unsolicited advice on using Viread as a first line therapy from Gilead, and then both began using Viread as a first line therapy. (TAC at ¶160.)

After considering the totality of Plaintiffs' allegations, the Court has serious concerns regarding whether Plaintiffs have adequately alleged that the off-label marketing scheme affected Gilead's sales figures during the second and third quarter of 2003 in a "material" sense. To be certain, the allegations of CW1 and CW2, without more, are insufficient to establish "materiality" under the PSLRA.[6] Plaintiffs' remaining allegations generally involve the pervasiveness of the off-label marketing scheme, the percentage of patients that were allegedly prescribed Viread off-label, and the doctors that received off-label material from Gilead. Whether these allegations, when read in conjunction with the testimony of CW1 and CW2, sufficiently constitute a "material" omission is ultimately a close question. However, the Court need not decide that issue because even assuming that Plaintiffs have sufficiently alleged "materiality," there is no question that Plaintiffs have failed to adequately allege loss causation.

B. Loss Causation

Allegations of "loss causation" are a necessary element of a § 10(b) claim. *Dura Pharmaceuticals, Inc. v. Broudo*, 125 S.Ct. 1627, 1631 (2005). The Supreme Court has recently clarified that merely alleging that a misrepresentation caused an inflated purchase price does not, without more, demonstrate loss causation. *Id.* at 1631-32. To "touch upon" an economic loss is insufficient; plaintiffs must demonstrate an

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[6] CW1's "belief' that 75% to 95% of all sales of Viread in the United States were the result of off-label marketing is apparently only based upon CW1's own off-label Viread sales. The fact that a large majority of CW1's own Viread sales resulted from off-label marketing does not raise an inference that *all Viread sales* in the United states resulted from similar means. CW2's allegations are problematic for similar reasons.

actual "causal connection" between the defendant's material misrepresentation and the economic loss suffered. *Id.* at 1633. The Ninth Circuit has held that a plaintiff sufficiently pleads "loss causation" by alleging that there was a steep drop in defendants' stock price upon revelation by the defendants of previously undisclosed facts. *In re Daou Systems Inc.*, 411 F.3d 1006, 1026 (9th Cir. 2005).

Defendants contend that Plaintiffs have failed to allege the element of loss causation. Defendants assert that Plaintiffs' loss causation allegations are flawed because Gilead disclosed the FDA's warning letter on August 7, 2003, but the drop in Gilead's share price did not occur until October 29, 2003. Defendants argue that the drop in the share price was a direct result of Gilead's October 28, 2003 statements, in which Gilead disclosed that its revenues for Viread in the third quarter of 2003 were less than in the previous quarter and that the company's earlier estimate of the level of second quarter inventory stocking by wholesalers had been too low. Thus, Defendants conclude that Plaintiffs have failed to establish a "causal connection" between the disclosure of the FDA's warning letter (containing the off-label marketing allegations) and the stock price drop.

Plaintiffs respond that the FDA warning letter caused Gilead's domestic sales—the overwhelming number of which were allegedly off-label—to substantially decline in comparison to what they would have been had the off-label marketing continued undiscovered. Plaintiffs assert that the sharp decline in Viread sales suggested that doctors—now alerted to Viread's safety problems and more limited approved uses—were less inclined to prescribe Viread. As a result, Plaintiffs contend that Gilead was unable to

continue increasing prescriptions to new patients in line with growth rates of past quarters. Thus, Plaintiffs conclude that Gilead's dismal October 28 sales report, combined with the prior revelations of Gilead's off-label marketing by the FDA, caused Gilead's stock price to drop 12% on October 29.

The Court finds that Plaintiffs' allegations regarding loss causation are simply too attenuated to withstand scrutiny under *Dura*. As an initial matter, the Court notes that none of Gilead's disclosures on or around October 28 directly related in any way to off-label marketing. Rather, the only disclosures about Defendants' off-label marketing occurred when the FDA warning letter became public on August 7, 2003 and again when Defendants filed their 10-Q on August 14, 2003. *See Dura*, 125 S. Ct. at 1634 ("The complaint's failure to claim that [ ] share price fell significantly after the truth became known suggests that the plaintiffs considered the allegation of purchase price inflation alone sufficient."). The record reflects that Gilead stock price actually rose following the public disclosure of the FDA letter and remained unchanged following the August 14 10-Q filing.

While Plaintiffs concede that the October 28 statements only discussed lower than expected sales numbers, they contend that the dismal financial numbers were a direct result of the disclosure of the off-label marketing scheme on August 7. Thus, Plaintiffs conclude they have sufficiently alleged a "causal connection" between the FDA letter and their losses. The Court disagrees. Plaintiffs contention relies upon the theory that doctors stopped prescribing Viread in such large quantities following the disclosure of the FDA letter, and that this change in prescribing patterns led to a drop in prescriptions that did not be-

come apparent until the October earning release. However, this theory is problematic for a very simple reason—the Court is unable to find these allegations in the TAC. As a result, these allegations cannot serve as the basis for denying a motion to dismiss.[7]

Moreover, Plaintiffs contend that the absence of a stock price drop following the disclosure of the FDA letter was a result of investors not suspecting "that almost all of Defendants' domestic sales depended on off-label marketing." (Plaintiffs' Opposition to Motion to Dismiss TAC at 27:20-21.) However, this argument is flawed because the record reflects that investors never actually learned the extent of Defendants' off-label marketing scheme. Neither Defendants, the FDA, nor a third party ever disclosed such information to the investing public.

Thus, when the TAC is analyzed in light of *Dura*, it is evident that Plaintiffs have not adequately alleged proximate causation and economic loss with respect to Gilead's alleged off-label marketing scheme. To be certain, Plaintiffs do not allege that a price drop immediately accompanied the disclosure of the FDA warning letter, and hence the Court is left to speculate as to what portion of the eventual loss, if any, should be attributed to the disclosure or whether the loss was caused by other factors. "But it should not prove burdensome for a plaintiff who has suffered an economic loss to provide defendant with some indication of the loss and the causal connection that the plaintiff has in mind." *Dura*, 125 S. Ct. at 1634. As in

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[7] In any event, this theory is in direct conflict with Gilead's actual disclosures on October 28, 2003, informing the market that new and total prescriptions increased as compared to the second quarter and as compared to the third quarter of the prior year.

Dura, Plaintiffs have failed to make such an indication in the TAC. Accordingly, the Court finds that Plaintiffs have failed to adequately plead loss causation.

C. RULE 20(A) LIABILITY

Section 20(a) of the Securities Exchange Act provides derivative liability for those who control others found to be primarily liable under the Act. *In re Ramp Networks, Inc. Sec. Lit.*, 201 F. Supp. 2d 1051, 1063 (N.D. Cal. 2002). Where a plaintiff asserts a section 20(a) claim based on an underlying violation of section 10(b), the pleading requirements for both violations are the same. *Id.*

Here, Plaintiffs assert that the individual Defendants are liable under this section because of an underlying violation of section 10(b). However, because Plaintiffs have failed to adequately plead the underlying 10b-5 violation, the section 20(a) claims must be dismissed as well.

D. DISMISSAL WITHOUT PREJUDICE

Leave to amend under Federal Rule of Civil Procedure 15 should be liberally granted. "Dismissal with prejudice and without leave to amend is not appropriate unless it is clear . . . that the complaint could not be saved by amendment." *Eminence Capital v. Aspeon Inc.*, 316 F.3d 1048, 1053 (9th Cir. 2003) (error to refuse leave to amend in a securities fraud case to allow plaintiff to plead scienter). Here, the Court notes that after the TAC was filed, *Dura* changed Ninth Circuit law with respect to the pleading of loss causation. Leave to amend is warranted where there has been an intervening change in the law. *See Wilcox v. First Interstate Bank, N.A.*, 815 F.2d 522, 530 (9th Cir. 1987). Accordingly, the Court dismisses the TAC without prejudice. The Plaintiffs should file an

amended complaint within thirty (30) days from the date of this Order.

CONCLUSION

In light of the heightened pleading standards of the PSLRA and the requirements of Federal Rule of Civil Procedure 12(b)(6), the Court GRANTS Defendants' 12(b)(6) motion to dismiss the TAC without prejudice.

IT IS SO ORDERED.

Dated: October 11, 2005

/s/ MARTIN J. JENKINS
MARTIN J. JENKINS
UNITED STATES DISTRICT JUDGE

APPENDIX D

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF
CALIFORNIA

No. C 03-4999 MJJ

In re GILEAD SCIENCES SECURITIES LITIGATION,

This Document Relates To: ALL ACTIONS

AMENDED ORDER *GRANTING* DEFENDANTS' 12(b)(6) MOTION TO DISMISS

INTRODUCTION

Before the Court is Gilead Sciences, Inc. ("Gilead"), John C. Martin, John F. Milligan, Mark L. Perry, Norbert W. Bischofberger, Anthony Carrociolo and William A. Lee's ("Defendants") Motion to Dismiss a federal securities fraud action brought against them by a class consisting of all purchasers of Gilead stock between July 14, 2003 and October 28, 2003. Defendants seek an Order dismissing the Consolidated Amended Class Action Complaint ("Amended Complaint") with prejudice under the heightened pleading requirements of the Private Securities Litigation Reform Act of 1995 ("PSLRA") and pursuant to Federal Rules of Civil Procedure 12(b)(6) and 9(b). For the following reasons, Defendants' motion is GRANTED with leave to amend.

FACTUAL ALLEGATIONS

This motion arises from an Amended Complaint ("Comp.") alleging securities fraud in violation of section 10(b) of the Securities Exchange Act and Rule 10b-5 promulgated thereunder against all Defendants, and violation of section 20(a) of the Securities Exchange Act. The Amended Complaint is brought on behalf of a class consisting of all persons who purchased or otherwise acquired Gilead stock between July 14, 2003 and October 28, 2003.

The allegations of Plaintiffs' complaint relate to Gilead's announcement in July 2003 of its financial results for the second quarter of 2003, and the impact its premier product, Viread, had on those results Viread is a groundbreaking antiretroviral drug used to treat HIV/AIDS that was introduced in 2001. On July 14, 2003, the first day of the class period, Gilead issued a press release entitled "Gilead Sciences Expects Second Quarter 2003 Financial Results Will Exceed Expectations," and stating, "[t]he increase in revenue was driven primarily by strong sales growth of Viread." The press release went on to say that Viread sales increased due to "broader prescribing patterns . . . as well as increases in U.S. wholesaler inventory levels in the second quarter." On the same day, *Bloomberg News* identified Gilead spokeswoman Amy Flood as stating that "[t]he main reason for the jump in Viread sales is an increase in prescriptions, not inventory stocking."

Two weeks later, on July 31, 2003, Gilead issued a press release containing its final results for the second quarter. Gilead announced that it had net revenues of $230.7 million for the quarter, of which $167 million related to Viread. Gilead went on:

> Viread sales growth was primarily driven by higher prescription volume, a significant increase in U.S. wholesaler inventories and a favorable European currency environment compared to the same quarter last year. Gilead estimates that increased stocking by U.S. wholesalers accounted for $25-30 million in Viread sales in the second quarter.

The press release contained warnings regarding the forward-looking statements and stated that the statements were "subject to certain risks and uncertainties, which could cause actual results to differ materially." Statements made during Gilead's earnings call of that same date, as well as on its Form 10-Q filed August 14, 2003, contained similar warnings.

Also on July 31, 2003, Gilead held a conference call with analysts and other investors regarding its financial results. During the call, an officer of Gilead stated:

> Of significant note, we believe that a substantial inventory build occurred in U.S. distributor channel during the second quarter as wholesalers anticipated the Viread price increase announced on June 27th. Though difficult to determine the exact figure for this inventory build, we estimate that wholesaler inventories increased by $25 to $30 million during the quarter . . . . Based on the U.S. inventory build up seen in the second quarter, we anticipate Viread sales for the third quarter will be at or below the sales level recognized this second quarter. We expect these inventories to be drawn down to more normal levels during this quarter.

On August 14, 2003, Gilead filed its Form 10-Q for the second quarter of 2003. This form confirmed the previously announced financial results. The Form 10-Q also discussed the inventory buildup: "We estimate that this higher stocking resulted in $25.0 to $30.0 million of additional sales during the second quarter, which may adversely impact sales in the third quarter as wholesalers return to more normal inventory levels and buying patterns." The form 10-Q also disclosed the existence of a July 19, 2003 letter issued by the FDA warning Gilead about certain aspects of its promotional practices of Viread.

On October 28, 2003, Gilead announced its financial results for the third quarter of 2003. Gilead announced net revenues of $194.1 million, and sales of Viread of $115.4 million. At that time, Gilead stated: "After reviewing NDC prescription trends, IMS inventory data and actual Viread sales, Gilead estimates there was approximately $33 to $37 million of inventory reduction by U.S. pharmaceutical wholesalers during the third quarter of 2003 following an equivalent inventory build during the second quarter of 2003." The next day, Gilead's stock dropped $7.46 per share from $59.46 per share to close at $52 per share. Approximately one month later, on December 2, 2003, Gilead's stock price had recovered the entire drop experienced on October 29 and closed at $59.83 per share.

Plaintiffs allege that for the period of at least September 2001 through, and subsequent to, the class period, Gilead engaged in the off-label marketing of Viread. Off-label marketing refers to the use for marketing purposes of information such as the result of clinical studies and other materials on the uses of and the efficacy of an FDA-approved product

that has not been approved by the FDA for inclusion in the product's package labeling. Pursuant to FDA guidelines, pharmaceutical manufacturers such as Gilead may only promote an FDA-approved drug consistent with the contents of its FDA-approved package labeling.

Plaintiffs allege that Gilead's off-label marketing activities began as early as September 2001 at Gilead's national sales meeting in Miami. There, sales and marketing employees allegedly were given information regarding Gilead's submission of Viread clinical data and information to the FDA and, with a "wink and a nod," were instructed to use this information to sell Viread even though Viread had yet to be approved by the FDA. The FDA approved Viread in October, 2001. Later, employees allegedly were instructed at numerous regional and national sales meetings by Gilead executives "overtly and covertly," to use off-label information to aggressively promote and sell Viread. At these meetings, employees allegedly would be provided off-label information such as updates on clinical trials of Viread in large group meetings and then told in subsequent smaller meetings to use this information to sell Viread. Defendants Martin, Perry, Lee, Milligan, and Bischofberger allegedly attended one or more of these regional and national sales meetings.

According to the Amended Complaint, Gilead received an Untitled FDA Letter on March 14, 2002, advising the company that its representatives had made false and misleading oral promotional statements at the December 2001 Interscience Conference on Antimicrobial Agents and Chemotherapy conference. According to the Untitled FDA Letter, Gilead falsely and misleadingly promoted Viread by stating

that it contained "no toxicities," was "extremely safe," and was "extremely well-tolerated," despite the fact that its boxed warning and Package Labeling advised to the contrary. The Untitled FDA Letter further ordered Gilead to "immediately cease making such violative statements," and required Gilead to submit a written response describing its intent and plans to comply with the FDA's directives. Plaintiff alleges that the false statements were made by Defendant Martin and it was company-wide knowledge that Martin was the cause of the Untitled FDA Letter. On March 21, 2002, Gilead responded stating that it was "commit[ted] to ensure that future violative statements are not made in the promotion of Viread." However, sixteen months later, on July 29, 2003, the FDA issued a second letter, notifying Gilead that it considered certain oral representations made by a Gilead representative at a promotional booth during a conference in April 2003 to be improper. This conference took place during Gilead's second fiscal quarter of 2003, just prior to Defendants' first class period announcement of outstanding Viread sales and financial results which exceeded market expectations. In response to and in compliance with this letter, on November 7, 2003, defendant Martin wrote a correction letter to the conference's attendees.

JUDICIAL NOTICE

In addition to the Motion to Dismiss the Amended Complaint, Defendants have filed a Request for Judicial Notice, and ask the Court to notice a number of documents. Federal Rule of Evidence 201 allows a court to take judicial notice of a fact "not subject to reasonable dispute in that it is . . . capable of accurate and ready determination by resort to sources whose accuracy can not reasonably be questioned."

Plaintiffs do not object to the Court's taking judicial notice of the requested documents.[1]

A. Documents Explicitly Referenced in the Amended Complaint

Initially, Defendants ask the Court to take judicial notice of specified press releases, one news article, and SEC filings explicitly referenced in the Amended Complaint under the "incorporation by reference" doctrine. This doctrine permits the Court to consider documents alleged in a complaint and whose authenticity no party questions, but which are not physically attached to [plaintiffs'] pleading." *Branch v. Tunnell*, 14 F.3d 449, 454 (9th Cir. 1994). Here, this includes press releases dated July 14 and July 31, 2003, a news article dated July 14, 2003, and Gilead's Form 10-Q filed with the SEC, all of which are attached to the Declaration of Grant Fondo and explicitly referenced in the Amended Complaint. Plaintiffs do not dispute the authenticity of any of these documents, or claim that Defendants documents contain errors. Absent such an argument, incorporation under *Branch* is warranted.

B. Allegations on Which the Complaint Implicitly Rely

The Court can take judicial notice of Exhibit D because "the Court may take judicial notice of documents on which allegations in the [complaint] necessarily rely, even if not expressly referenced in the [complaint], provided the authenticity of those documents is not in dispute," *In re Calpine Corp. Sec.*

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[1] However, Plaintiffs object to Defendants' Motion for Judicial Notice only if Defendants seek to have the Court take judicial notice of the truth of the requested documents. The Court does not restrict its taking of judicial notice in this way.

Litig, 288 F. Supp. 2d 1054, 1076 (N.D. Cal. 2003). Plaintiffs necessarily rely upon this conference call because they claim that Defendants perpetuated a fraud on the market with the July 31, 2003 financial announcement and estimated inventory build-up. Therefore, the statements made in the conference call directly relate to the claim of fraud on the market and the transcript reflects information available to the market at the time.

C. Public Filings With the SEC

Defendants ask the Court to take judicial notice of publically available documents that Defendants filed with the SEC. "In a securities action, a court may take judicial notice of public filings when adjudicating a motion to dismiss . . . ." *Calpine*, 288 F. Supp. 2d at 1076. Accordingly, the Court takes judicial notice of these documents.[2]

LEGAL STANDARDS

A. Rule 12(b)(6)

A court may dismiss a complaint pursuant to Federal Rule of Civil Procedure 12(b)(6) for either lack of a cognizable legal theory or the pleading of insufficient facts under an adequate theory. *Robertson v. Dean Witter Reynolds, Inc.*, 749 F.2d 530, 533-34 (9th Cir. 1984). When deciding upon a motion to dismiss for failure to state a claim upon which relief can be granted pursuant to FRCP 12(b)(6), a court must take all of the material allegations in plaintiff's complaint as true, and construe them in the light most favorable to plaintiff.

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[2] The Court refuses to take judicial notice of Ex. O (April 2003 press release), as it does not fit into any of the recognized categories allowing for judicial notice.

Parks School of Business, Inc, v. Symington, 51 F.3d 1480, 1484 (9th Cir. 1995). Moreover, a complaint should not be dismissed unless a plaintiff could prove no set of facts in support of his claim that would entitle him to relief. *Id.*

In the context of a motion to dismiss, review is limited to the contents in the complaint. *Allarcom Pay Television, Ltd v. General Instrument Corp.*, 69 F.3d 381, 385 (9th Cir. 1995). When matters outside the pleading are presented to and accepted by the court, the motion to dismiss is converted into one for summary judgment. Where such a conversion takes place, all parties must be given an opportunity to present all material made pertinent to such a motion by Rule 56. *In re Pacific Gateway Exchange, Inc. Sec. Lit.*, 169 F. Supp. 2d 1160, 1164 (N.D. Cal 2001); *see also* Fed. R. Civ. P. 12(b). However, matters properly presented to the court, such as those attached to the complaint and incorporated within its allegations, may be considered as part of the motion to dismiss. *See Hal Roach Studios, Inc. v. Richard Feiner & Co.*, 896 F.2d 1542, 1555 n.19 (9th Cir. 1989).

Where a plaintiff fails to attach to the complaint documents referred to in it, and upon which the complaint is premised, a defendant may attach to the motion to dismiss such documents in order to show that they do not support plaintiff's claim. *See Pacific Gateway Exchange*, 169 F. Supp. 2d at 1164; *Branch v. Tunnell*, 14 F.3d 449, 44 [sic] (9th Cir. 1994), *cert denied*, 512 U.S. 1219 (1997). Thus, the district court may consider the full texts of documents that the complaint only quotes in part. *See In re Stay Electronics Sec. Lit.*, 89 F.3d 1399, 1405 n.4 (1996), *cert denied*, 520 U.S. 1103 (1997). This rule precludes plaintiffs "from surviving a Rule 12(b)(6) motion by

deliberately omitting references to documents upon which their claims are based." *Parrino v. FHP, Inc.*, 146 F.3d 699, 705 (9th Cir. 1998).

B. Section 10(b) and Rule 10b-5

Section 10(b) of the Securities Exchange Act provides, in part, that it is unlawful "to use or employ in connection with the purchase or sale of any security registered on a national securities exchange or any security not so registered, any manipulative or deceptive device or contrivance in contravention of such rules and regulations as the [SEC] may prescribe." 15 U.S.C. § 78j(b).

Rule 10b-5 makes it unlawful for any person to use interstate commerce

(a) To employ any device, scheme, or artifice to defraud.

(b) To make any untrue statement of material fact or to omit to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading, or

(c) To engage in any act, practice, or course of business which operates or would operate as a fraud or deceit upon any person, in connection with the purchase or sale of any security.

17 C.F.R. § 240.10b-5.

To be actionable under section 10(b) and Rule 10b-5, a plaintiff must allege (1) a misrepresentation or omission; (2) of material fact; (3) made with scienter; (4) on which the plaintiff justifiably relied; (5) that proximately caused the alleged loss. *See Binder v.*

Gillespie, 184 F.3d 1059, 1063 (9th Cir. 1999), Additionally, as in all actions alleging fraud, plaintiffs must state with particularity the circumstances constituting fraud. Fed. R. Civ. P. 9(b).

C. Section 20(a)

Section 20(a) of the Securities Exchange Act ("Exchange Act") provides derivative liability for those who control others found to be primarily liable under the Act. *In re Ramp Networks, Inc. Sec. Lit.*, 201 F. Supp. 2d 1051, 1063 (N.D. Cal. 2002). Where a plaintiff asserts a section 20(a) claim based on an underlying violation of section 10(b), the pleading requirements for both violations are the same. *Id.*

D. Private Securities Litigation Reform Act

In 1995, Congress enacted the PSLRA to provide "protections to discourage frivolous [securities] litigation." H.R. Conf. Rep. No. 104-369, 104th Cong., 1st Sess. at 32 (1995)) [sic] (Nov. 28, 1995). The PSLRA strengthened the pleading requirements of Rules 8(a) and 9(b). Actions based on allegations of material misstatements or omissions under the PSLRA must "specify each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and, if an allegation regarding the statement or omission is made on information and belief, the complaint shall state with particularity all facts on which that belief is formed." 15 U.S.C. §78u-4(b)(1).

The PSLRA also heightened the pleading threshold for causes of action brought under Section 10(b) and Rule 10b-5. Specifically, the PSLRA imposed strict requirements for pleading scienter. A complaint under the PSLRA must "state with particularity facts giving rise to a strong inference that the defendant

acted with the required state of mind." 15 U.S.C. § 78u-4(b)(2). The Ninth Circuit, in interpreting the PSLRA, has held that "a private securities plaintiff proceeding under the [PSLRA] must plead, in great detail, facts that constitute strong circumstantial evidence of deliberately reckless or conscious misconduct." *In re Silicon Graphics Inc.*, 183 F.3d 970, 974 (9th Cir. 1999). If the complaint does not satisfy the pleading requirements of the PSLRA, upon motion by the defendant, the court must dismiss the complaint. *See* 15 U.S.C, §78u-4(b)(1)

ANALYSIS

In order to support its claims under the PLSRA, Plaintiffs must first specify a "statement alleged to have been misleading." 15 U.S.C. § 78u-4(b)(1). Plaintiffs argue that statements from four separate incidents attributed to Defendants were false and misleading.[3]

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[3] Before engaging in the pertinent legal analysis, the Court deems it necessary to highlight the theory of Plaintiffs' action. In their original complaint, Plaintiffs alleged that Defendants gave a false impression of the true demand for Viread by understating the degree to which drug wholesalers had increased their inventory levels. To that end, Plaintiffs' complaint focused primarily upon Defendants' July 31, 2003, estimate of inventory stocking numbers ($25 to $30 million) and Defendants' revision of those numbers on October 28, 2003 ($30 to $37 million). In fact, nearly all of the statements that Defendants allege were false involve Gilead's public statements regarding its estimate of the impact inventory stocking had on the company's second quarter financial results. This is evidenced by the fact that Plaintiffs' class period began on July 14, 2003 and ended on October 28, 2003.

However, Plaintiffs' Amended Complaint alleged new facts, upon which Plaintiffs now primarily rely. Plaintiffs contend that Defendants engaged in improper off-label marketing of Viread

Initially, Plaintiffs contend that statements from Gilead's press release on July 14, 2003 were false. Specifically, the press release stated that "[t]he increase in revenue was driven primarily by strong sales growth of Viread." The press release went on to state that Viread sales increased due to "broader prescribing patterns . . . as well as increases in U.S. wholesaler inventory level in the second quarter in anticipation of a Viread price increase." On the same day, the *Bloomberg News* identified Gilead spokeswoman Amy Flood as stating that "[t]he main reason for the jump in Viread sales is an increase in prescriptions, not inventory stocking." Plaintiffs also assert that this statement was false and misleading.

Next, Plaintiffs allege that Gilead's July 31, 2003 press release contained false statements. In the press release, the company stated that "Viread sales growth was primarily driven by higher prescription volume, a significant increase in U.S. wholesaler inventories and a favorable European currency environment . . . . Gilead estimates that increased stocking by U.S. wholesalers accounted for $25-30 million of Viread sales in the second quarter." The

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that lead to increased Viread prescriptions. Consequently, Plaintiffs allege that Viread's 2003 second quarter sales report overstated the true demand for the drug. Plaintiff assert that Defendants violated the PSLRA by not disclosing the off-label marketing profits, as these profits were material adverse facts necessary to make the company's second quarter statement not misleading. In their Opposition to Defendants' Motion to Dismiss, Plaintiffs allege that Gilead's misrepresentations regarding overstocking, in combination with the company's off-label marketing scheme, "support an inference that Defendants knew, or were deliberately reckless in ignoring, that the Company materially understated its reports of sales to wholesalers in Second Quarter 2003."

press release also stated that the company was "focused on continuing this sales momentum and increasing our market share through robust clinical data and label expansions . . . ." Plaintiffs assert that these statements were false.

Finally, Plaintiffs assert that Gilead's Second Quarter 2003 10-Q contained false statements. Specifically, the company stated that "[t]he increase in product sales is due to the significant increase in the volume of sales of Viread." The Second Quarter 2003 10-Q also stated that "[t]he significant increase in Viread sales is due to increased prescription volume."

Defendants move the Court to dismiss the Amended Complaint with prejudice pursuant to the PSLRA and Federal Rules of Civil Procedure 8(a), 8(e), 9(b), and 12(b)(6) on several grounds. Defendants argue that: 1) Plaintiffs fail to plead facts with the required particularity that Defendants' public statements were false and misleading at the time they were made; 2) the Amended Complaint fails to plead scienter; 3) the Safe Harbor provisions of the Reform Act bars claims based on Defendants' forward looking statements; 4) Plaintiffs fail to plead that defendants Martin, Milligan, Perry, Bischofberger, Carraciolo, and Lee are liable as control persons under section 20(a) of the Exchange Act.

A. Falsity and Scienter

In order to avoid having their action dismissed, Plaintiffs must "plead with particularity either the alleged misleading statements or scienter[.]" *In re Fritz Cos. Sec. Litig.*, 282 F Supp. 2d 1105, 1112 (N.D. Cal 2003). The Ninth Circuit has articulated the rule as follows:

> Because falsity and scienter in private securities fraud cases are generally strongly inferred from the same set of facts, we have incorporated the dual pleading requirements of 15 U.S.C §§ 78u-4(b)(1) and (b)(2) into a single inquiry. In considering whether a private securities fraud complaint can survive dismissal under Rule 12(b)(6), we must determine whether particular facts in the complaint, taken as a whole, raise a strong inference that defendants intentionally or deliberate recklessness made false or misleading statements to investors, Where pleadings are not sufficiently particularized or where, taken as a whole, they do not raise a "strong inference" that misleading statements were knowingly or deliberate recklessness made to investors, a private securities fraud complaint is properly dismissed under Rule 12(0(6).

Ronconi v. Larkin, 253 F.3d 423, 429 (9th Cir. 2001) (citations and internal quotation marks omitted).

1. Defendants' Misrepresentations Regarding Wholesaler Overstocking

Defendants argue that Plaintiffs have not pointed to any evidence to indicate that any of Defendants' statements regarding wholesaler overstocking were false or misleading. Defendants assert that Gilead's increase in revenues in the second quarter of 2003, was in fact, driven by strong sales of Viread. Defendants also assert that the growth in Viread sales was driven by higher prescription volumes and an increase in wholesaler inventories. Defendant also contend that their estimate of the inventory stocking numbers in July of 2003 ($25 to $30 million) was based on the best available data at the time. In essence, Defendants assert that the statements chal-

lenged by Plaintiffs were not false, misleading, or even equivocal, but were in fact entirely true.

Plaintiffs contend that the Amended Complaint adequately details the manner in which Defendants materially understated Viread sales to wholesalers in the July 31 press release. Plaintiffs argue that the "significant shift in wholesaler sales from $25 to $30 million to $33 to $37 million" is strong evidence that Defendants' estimates were misleading. Plaintiffs also argue that the difference between the estimates is "material" and must be considered by the Court. Regarding Defendants' other challenged statements, Plaintiffs assert that given the announced price increase of Viread, Defendants must have known that Gilead's higher second quarter sales figures were related to increased inventory stocking of Viread, and not increased prescription sales.

The Court finds that Plaintiffs have failed to allege any facts inconsistent with the conclusion that Gilead's 2003 second quarter financial reports were made in good faith and based on the best information available at the time. Most importantly, Plaintiffs have not referenced a single document or conversation suggesting Defendants knew that the July 31 estimate of the second quarter inventory stocking numbers was too low at the time the estimate was made public. It is noteworthy that the press release contained only an "estimate" of the increased stocking numbers, and the press release specifically warned investors of Gilead's limited ability to accurately estimate inventory levels. In fact, the press release stated that Gilead was making a "great deal of assumptions" and "rely[ing] on incomplete data" in making the estimate. Moreover, as noted by Defendants, Gilead's revised October estimates re-

garding increased stocking numbers were not significantly different than the original July estimate. Additionally, Plaintiffs have not alleged facts that would tend to show that the growth in Viread sales was not driven, at least in part, by higher prescription sales.[4] Given these considerations, the Court finds that Plaintiffs have not alleged sufficient facts to demonstrate that any of Defendants' statements regarding wholesaler overstocking were false or misleading at the time the statements were made,

2. Off-Label Marketing Scheme

While not conceding the issue of wholesaler stocking, Plaintiffs spend the majority of their Opposition to Defendants' Motion to Dismiss focusing on Gilead's alleged off-label marketing scheme. Plaintiffs allege that the off-label marketing scheme was "the cornerstone of [Gilead's] business." Plaintiffs conclude that Defendants had a duty to disclose the details of the off-label marketing scheme, and the subsequent FDA warning letters, to its investors.[5] According to Plain-

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[4] In a similar case to this one, the plaintiffs had alleged that the Company's executives knew that wholesaler purchases of a pharmaceutical company's product in one quarter would lead to overstocking and, therefore, would result in fewer sales in the next quarter, while at the same time defendants were publically projecting strong future sales. *Lipton v. Pathogenesis Corp.*, 284 F.3d 1027 (9th Cir. 2002). The court found that the complaint's reference to internal reports on sales data and patient demand data was insufficient to support a PSLRA claim. *Id.* at 1036. "Plaintiffs do not mention a specific [ ] document relied on by defendants such as a particular [ ] report, graph or chart. Nor do they detail with particularity the content of such data." *Id.* Here, Plaintiffs have not referenced a single internal report on Gilead's sales data that could have provided information (scienter) to Defendants.

[5] Thus, it appears that Plaintiffs are bringing their action pursuant to 15 U.S.C. § 78u-4(b)(1)(B), which instructs Plain-

tiffs, Defendants' off-label marketing enabled the company to create the appearance of increased prescriptions and demand for Viread. As a result, wholesalers were encouraged to stock up on Viread ahead of Gilead's announced price increase. Plaintiffs further allege that Gilead's second quarter sales estimates, including wholesaler stocking, were tainted by the off-label marketing scheme because the marketing "created an artificial and illusory demand for Viread."

Defendants argue that Plaintiffs never allege that anyone at Gilead (including Defendants) actually participated in improper off-label marketing activities. Defendants also contend that Plaintiffs have not shown a connection between Gilead's alleged off-label marketing activities and actual sales of Viread.

The Court initially considers whether Plaintiffs have adequately alleged that Defendants engaged in an illegal off-label marketing scheme. The Amended Complaint states that Plaintiffs' confidential witnesses (CW1 and CW2) attended various meetings at which Gilead's sales and marketing team received specific instructions to market Viread off-label. Specifically, according to the Amended Complaint, CW1 and CW2 attended the 2002 Los Angeles Regional Meeting at which Defendants Meyers, Perry, and Martin were in attendance. A similar meeting took place in Las Vegas during 2003 and Defendants Milligan, Perry, Bischofberger, and Martin were allegedly present. Additionally, a company meeting took place in Orlando during 2003, and CW 1 and

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tiffs to allege that Defendants "omitted to state a material fact necessary in order to make the statements made, in light of the circumstances in which they were made, not misleading."

CW 2 recall that Defendants Martin, Milligan, Bischofberger, Lee, and Perry were in the room when specific instructions were given to sales and marketing personnel to utilize off-label information to push sales of Viread. Moreover, both CW1 and CW2 attended various other meetings, not attended by Defendants, in which Gilead presenters provided off-label information and encouraged them to use the information to sell Viread.

In addition to the allegations of CW1 and CW2, the Court must consider the FDA letters that were sent to Gilead. The March 14, 2002 letter advised Gilead that its promotional activities were violating the Federal Food, Drug, and Cosmetic Act. These violations arose from "false and misleading oral statements about Viread" made by Viread representatives in Chicago during 2001. The letter advised Gilead to "immediately cease making such violative statements and . . . cease . . . distribution or use of any promotional materials for Viread that contain violative . . . . statements." The FDA sent another letter to Gilead on July 29, 2003, and stated that Gilead representatives had "minimized important risk information and broadened the indication for Viread." As a result of these violations, the FDA instructed Gilead to provide the agency with a detailed response regarding its promotional activities of Viread.

Defendants contend that CW 1 and CW 2 never allege that Defendants actually participated in improper off-label marketing activities. Defendants are correct. Indeed, CW1 and CW 2 only allege that Gilead representatives were instructed to engage in such activity, not that such activity actually took place. However, the Court must also consider the FDA letters sent to Gilead. In those letters, the FDA

clearly confirms that Gilead representatives were actively engaging in the off-label marketing of Viread with the intent to increase Viread sales. Therefore, when the allegations of CW1 and CW2 are considered in light of the FDA's letters to Gilead, it becomes apparent that Plaintiffs have alleged sufficient facts to raise a strong inference that Defendants' had knowledge of the company's off-label marketing scheme.

Yet, this conclusion does not end the Court's inquiry. Plaintiffs must also establish a connection between the company's off-label marketing activities and the 2003 second quarter reports that Plaintiffs allege were false and misleading. In other words, Plaintiffs must allege that Gilead's off-label marketing scheme was a "material fact" that needed to be disclosed to investors along with the 2003 second quarter sales reports.[6] *See* 15 U.S.C. § 78u-4(b)(1)(B). Plaintiffs have not carried this burden. Specifically, Plaintiffs have not alleged that any sales of Viread during the second quarter of 2003 were the result of improper off-label marketing activities. In fact, Plaintiffs do not identify a single prescription written for Viread that was allegedly generated by off-label marketing activity. Under the heightened pleading standard required in PSLRA cases, the Court cannot simply assume that Gilead's off-label marketing of

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[6] It is noteworthy that the July 29, 2003 warning letter from the FDA was disclosed to the public on August 7, 2003, and referenced in Gilead's second quarter Form 10-Q filed with the SEC on August 14, 2003. Interestingly, the record reveals that the public announcement of the FDA letter did not have an adverse affect on Gilead's stock price. This fact weighs against a finding that Defendants' off-label marketing scheme was a "material fact" requiring disclosure to investors.

Viread necessarily resulted in increased sales of that drug. Instead, Plaintiffs must allege facts to bridge this logical gap. Plaintiffs have failed to do so.

Furthermore, even assuming Plaintiffs had alleged that such sales took place, Plaintiffs would also have to allege that those sales were "material" to the 2003 second quarter reports. While Plaintiffs may not be required to detail the impact of Viread's off-label marketing on a sale-by-sale basis, Plaintiffs must allege facts that show a relationship between the off-label marketing of Viread, related sales of Viread, and the manner in which those sales affected Gilead's 2003 second quarter financial reports. Plaintiffs have alleged no such facts.

3. Stock Sales

Plaintiffs also rely on stock sales by the individual Defendants as an indication of their scienter. Generally, stock sale allegations can not raise an inference of scienter unless Plaintiffs allege specific facts showing that the sales were "dramatically out of line with prior trading practices at times calculated to maximize the personal benefit from undisclosed inside information." *Silicon Graphics*, 183 F.3d at 986. Among the relevant factors for a court to consider are: 1) the amount and percentage of shares sold by insiders; 2) timing of the sales; and 3) whether the sales were consistent with the insider's prior trading history. *Id.*

Defendant Martin sold 50,000 shares of Gilead stock, 2.62% of his total shares, during the class period. Defendant Bischofberger sold 90,020 shares, 9.47% of his total shares, during the class period. Defendant Perry sold 52,344 shares, 10.95% of his total shares, during the class period. Defendant Lee

sold 15,000 shares, 4.03% of his total shares, during the class period. Defendant Milligan sold 11,000 shares, 5.45% of his total shares, during the class period. Defendant Carraciolo sold 324,601 shares, 100% of his total shares, during the class period.

In light of the three factors above, these sales are not sufficiently suspicious to raise an inference of scienter. Other than Mr. Carraciolo, none of the individual defendants sold more than eleven percent of their holdings in Gilead during the class period.[7] *See Ronconi*, 253 F.3d at 435 (suggesting that sales of 10-17% of holdings was not suspicious). Collectively, the individual defendants sold just over eight percent of their share. Moreover, with the exception of Mr. Carraciolo, the individual defendants sold a roughly proportional number of shares in the third quarter of 2003 (the class period) as in the second quarter of 2003. Such sales are not sufficiently suspicious.

Plaintiffs allege that the timing of the stock sales are suspicious because Defendants Perry and Bischofberger sold their stock during the first week of August 2003, before the company disclosed that it had received a warning letter from the FDA. The Court disagrees. These sales represent only a small percentage of the total sales the Plaintiffs allege are

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[7] Even though Mr. Carraciolo sold 100% of his shares in Gilead, his sales represent a relatively insignificant portion of the allegedly suspicious sales. It is also relevant that Mr. Carraciolo had become a company officer on July 30, 2003, and thus the Court has no context in which to infer that Mr. Carraciolo's sales were suspicious. *See Silicon Graphics*, 183 F.3d at 987 ("And although [defendant] had never sold such a large quantity of stock, he had only been with [the company] for a year and had no significant trading history for purposes of comparison.").

suspicious. *See Ronconi*, 253 F.3d at 435 (stating that when corporate insiders collectively fail to seize a prime opportunity to "gain[ ] market advantage from as yet undisclosed bad news," an inference of scienter is negated). Therefore, the Court also does not find the timing of the stock sales suspicious.

4. Allegations as a Whole

In sum, the Amended Complaint "lacks sufficient detail and foundation necessary to meet either the particularity or strong inference requirements of the PSLRA." *Silicon Graphics*, 183 F.3d at 984. In *No. 84 Employer-Teamster Joint Council Pension Trust Fund v. America West Holding Corp.*, 320 F.3d 920 (9th Cir. 2003), the plaintiffs alleged that officers of America West Airlines had artificially inflated the company's stock prices. In support of their case, the plaintiffs alleged specific omissions and misrepresentations by the company's officers regarding deferred maintenance costs, unsafe maintenance practices, an ongoing investigation by the Federal Aviation Administration, and highly suspicious stock sales, in which most of the individual defendants sold 100% of their shares. *Id.* at 938-42. Viewing the totality of the allegations, the court held that the plaintiffs "raise[d] a strong inference that Defendants knew that the maintenance problems were ongoing and, thus, that the statements made by America West were false." *Id.* at 942.

Unlike the situation in *America West*, Plaintiffs have failed to allege particularized facts that could lead the Court to infer that Defendants knowingly misrepresented the details of Gilead's 2003 second quarter sales numbers. Even when the alleged misrepresentations regarding wholesaler stocking are considered together with the off-label marketing scheme

and the challenged stock sales, Plaintiffs have failed to set forth adequate corroborating details and facts to support their allegations under the PSLRA pleading standard.[8] *See America West*, 320 F.3d at 945 (holding that the allegations must be considered to their totality in determining whether plaintiffs have met the PSLRA standard).

RULE 20(a) LIABILITY

Section 20(a) of the Securities exchange Act provides derivative liability for those who control others found to be primarily liable under the Act. *In re Ramp Networks, Inc. Sec. Lit.*, 201 F. Supp. 2d 1051, 1063 (N.D. Cal. 2002). Where a plaintiff asserts a section 20(a) claim based on an underlying violation of section 10(b), the pleading requirements for both violations are the same. *Id.*

Here, Plaintiffs assert that the individual Defendants are liable under this section because of an underlying violation of section 10(b). However, because Plaintiffs have failed to adequately plead the underlying 10b-5 violation, the section 20(a) claims must be dismissed as well.

DISMISSAL WITHOUT PREJUDICE

Leave to amend under Federal Rule of Civil Procedure 15 should be liberally granted. "Dismissal with prejudice and without leave to amend is not appropriate unless it is clear . . . that the complaint could not be saved by amendment." *Eminence Capital v. Aspeon Inc.*, 316 F.3d 1048, 1053 (9th Cir. 2003)

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[8] Since Plaintiffs have not met the PSLRA pleading standard, the Court does not need to decide whether Defendants' statements fall within the safe harbor provision under 15 U.S.C. § 78u-5(c)(1)(A) or (B).

(error to refuse leave to amend in a securities fraud case to allow plaintiff to plead scienter). Here, it is possible that Plaintiffs could remedy their significant pleading defects in an amended complaint by adding detailed factual support for their allegations of false or misleading statements, and demonstrating that Defendants had the requisite scienter at the time the statements were made. Accordingly, the Court dismisses the Amended Complaint without prejudice. The Plaintiffs should file an amended complaint within thirty (30) days from the date of this Order.

CONCLUSION

After consideration of the Amended Complaint in light of the heightened pleading standards of the PSLRA and the requirements of Federal Rule of Civil Procedure 12(b)(6), the Court GRANTS Defendants' 12(b)(6) motion to dismiss without prejudice.

IT IS SO ORDERED.

Dated: January 26, 2005

/s/
MARTIN J. JENKINS
UNITED STATES DISTRICT JUDGE

APPENDIX E

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

[Filed OCT. 9, 2008]

No. 06-16185
D.C. No. CV-03-04999-MJJ
Northern District of California, San Francisco

In re: GILEAD SCIENCES SECURITIES LITIGATION.

RICK HARTMAN, on behalf of himself and all others similarly situated; TRENT ST. CLARE; TERRY JOHNSON,
Plaintiff-Appellants,

v.

GILEAD SCIENCES, INC.; JOHN C. MARTIN; JOHN F. MILLIGAN; MARK L. PERRY; NORBERT W. BISCHOFBERGER; ANTHONY CARRACIOLO; and WILLIAM LEE,
Defendants-Appellees.

ORDER

Before: KOZINSKI, Chief Judge, HAWKINS, and COWEN,* Circuit Judges.

The panel has voted to deny the petition for rehearing. Chief Judge Kozinski and Judge Hawkins have voted to deny the petition for rehearing en banc. Judge Cowen has recommended denying the en banc petition.

The full court has been advised of the petition for rehearing en banc and no Judge has requested a vote

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* The Honorable Robert E. Cowen, Senior United States Circuit Judge for the Third Circuit, sitting by designation.

on whether to rehear the matter en banc. Fed. R. App. P. 35.

The petition for rehearing and petition for rehearing en banc are DENIED.

No. 08-1021

FILED
MAR 16 2009
OFFICE OF THE CLERK
SUPREME COURT, U.S.

IN THE

Supreme Court of the United States

GILEAD SCIENCES, INC., JOHN C. MARTIN, JOHN F. MILLIGAN, MARK L. PERRY, NORBERT W. BISCHOFBERGER, ANTHONY CARRACIOLO AND WILLIAM A. LEE,

Petitioners,

v.

TRENT ST. CLARE AND TERRY JOHNSON, ON BEHALF OF THEMSELVES AND ALL OTHERS SIMILARLY SITUATED,

Respondents.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

BRIEF OF RESPONDENTS IN OPPOSITION TO PETITION FOR WRIT OF CERTIORARI

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March 16, 2009

WILSON-EPES PRINTING CO., INC. – (202) 789-0096 – WASHINGTON, D. C. 20002

QUESTION PRESENTED

Whether this Court's requirement in *Dura Pharmaceuticals, Inc. v. Broudo*, 544 U.S. 336, 346 (2005) – that loss causation be pled by "fair notice of what the plaintiff's claim is and the grounds upon which it rests" – was satisfied by the Ninth Circuit's holding that investors pled "sufficient detail to give defendants ample notice of [Investors'] loss causation theory, and to give us some assurance that the theory has a basis in fact."

PARTIES TO THE PROCEEDING

Petitioners, Defendants-Appellees below, are Gilead Sciences, Inc. and its officers and executives. Respondents, Plaintiffs-Appellants below, are Trent St. Clare and Terry Johnson, on behalf of themselves and a proposed class of investors who purchased publicly traded securities of Gilead between July 14, 2003 and October 28, 2003.

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IN THE

Supreme Court of the United States

No. 08-1021

GILEAD SCIENCES, INC., JOHN C. MARTIN, JOHN F. MILLIGAN, MARK L. PERRY, NORBERT W. BISCHOFBERGER, ANTHONY CARRACIOLO AND WILLIAM A. LEE,

Petitioners,

v.

TRENT ST. CLARE AND TERRY JOHNSON, ON BEHALF OF THEMSELVES AND ALL OTHERS SIMILARLY SITUATED,

Respondents.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

BRIEF OF RESPONDENTS IN OPPOSITION TO PETITION FOR WRIT OF CERTIORARI

I. INTRODUCTION

This case arises from the Ninth Circuit's correct application of *Dura Pharmaceuticals, Inc. v. Broudo*, 544 U.S. 336 (2005), to the facts alleged in Respondents-Plaintiffs' complaint. There is no reason for this Court to grant certiorari.

In *Dura*, this Court provided a standard for pleading loss causation in securities fraud cases that requires plaintiffs to set forth a theory of causation

accompanied by a showing that it is plausible, noting that this should not create a heavy pleading burden. *Id.* at 346-47. The Court assumed that Federal Rule of Civil Procedure 8(a)(2)'s "short and plain statement" requirement applied. *Id.* at 346.[1]

In the slightly less than four years since *Dura*, six circuits have applied it—six have not yet had the opportunity. As will be demonstrated below, the decisions are harmonious and reflect an understanding of what *Dura* requires. There is no division among the circuits. This case does not present any new statute to be interpreted, any changed circumstances, nor a deviation by the court below from any principle established by this Court. Given the consistent application of *Dura* and the limited experience under it, revisiting its standard is extremely premature.

Petitioners' attempt to create a split in the circuits reflects their dissatisfaction with the Ninth Circuit's fact-bound finding that Respondents alleged a plausible theory of loss causation. Petitioners present no valid basis for certiorari, instead inappropriately asking this Court to act as a court of correction. The Petition should be denied.

Indeed, even if there were some reason for this Court to revisit the question of whether Rule 8 or Rule 9 applies to pleading loss causation in a

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[1] Indeed, defendants in *Dura* suggested that this Court elevate the pleading requirement for loss causation to a Rule 9(b) standard—and this Court declined to do so. Justice Ginsburg emphatically rejected defendants' assertion: "I thought you pointed to the 9(b) pleading rule because fraud must be pleaded with particularity, but causation does not, not under the rules and not under the statute." *Dura Pharms., Inc. v. Broudo*, No. 03-932, 2005 U.S. TRANS LEXIS 4, at *19 (Jan. 12, 2005).

securities fraud complaint, that issue is not properly presented by this case because the Ninth Circuit explicitly held that "under either Rule 8 or Rule 9, the Investors have sufficiently pleaded loss causation." *In re Gilead Scis. Sec. Litig.*, 536 F.3d 1049, 1056, 1058 (9th Cir. 2008) ("Our review of the Investors' complaint convinces us that the October drop in stock price was plausibly caused by the Warning Letter. . . . Investors' complaint offers sufficient detail to give defendants ample notice of [Investors'] loss causation theory, and to give us some assurance that the theory has a basis in fact.").[2]

II. STATEMENT OF THE CASE

The operative complaint—Plaintiffs' Fourth Amended Complaint, filed on December 2, 2005 ("Complaint")—is the *first* complaint filed in this matter after this Court's decision in *Dura* changed the law in the Ninth Circuit regarding pleading loss causation. As Petitioners concede (Pet. 10),[3] the factual basis for loss causation—that "Gilead misled the investing public by representing that demand for its most popular product was strong without disclosing that unlawful marketing was the cause of that strength" (*Gilead*, 536 F.3d at 1050)—has been alleged since the very first complaint filed after the appointment of lead plaintiffs. Indeed, the district court found that "Plaintiffs have adequately alleged that Defendants engaged in an illegal off-label

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[2] Citations, footnotes, and internal quotations omitted and emphasis added, unless otherwise noted.

[3] "Pet. __" designates a page in the Petition for a Writ of Certiorari.

marketing scheme" (ER 25),[4] holding in its first and second orders that "Plaintiffs have alleged sufficient facts to raise a strong inference that Defendants had knowledge of the company's off-label marketing scheme." ER 12, 25. Petitioners' relentless characterization of a "sue-first-develop-a-story-later approach" (Pet. 30) is simply inaccurate.

The Complaint properly alleges loss causation. On July 14, 2003, Petitioners announced strong financial results for the second quarter of 2003; the market immediately responded by increasing the stock price of Gilead Sciences, Inc. ("Gilead") by 13.4% overnight. ER 78-79 ¶¶174, 180. The Complaint alleges that those results concealed fraud: that demand for Gilead's key drug, Viread, was artificially inflated because 75%-95% of all sales were caused by off-label marketing. ER 34 ¶9, 68-76 ¶¶141-65. Petitioners' practice was publicly exposed on August 7, 2003, when the U.S. Food and Drug Administration ("FDA") published a Warning Letter—Gilead's second on this subject—chastising Gilead for creating "significant public health and safety concerns" and requiring that Gilead immediately cease off-label marketing practices, disseminate correct information, and retrain its employees. ER 65¶125, 82¶191. The market did not respond because Petitioners continued to conceal the extent to which Gilead's business model depended on unlawful off-label marketing. ER 82-83 ¶¶191, 194-95. Prescription rates did respond, however, dropping sharply and modestly recovering to produce slower growth—as compared with earlier quarters—thus impacting Gilead's third quarter sales numbers and revealing

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[4] "ER __" designates a page in the Excerpts of Record filed in the Ninth Circuit.

the true demand for FDA-approved applications of Viread. ER 85¶¶200-01. Wholesalers, observing the decreased demand, drew inventory down well below the industry standard. ER 86¶204. On October 28, 2003, Petitioners announced Gilead's results for the third quarter of 2003, revealing Gilead's true financial condition; the market immediately responded, dropping Gilead's stock price 12% overnight on trading volume that was 1400% above average. ER 86-88¶¶205, 208, 210-11, 99-100¶¶234, 237.

A. Summary of Complaint's Factual Allegations by the Ninth Circuit

In an opinion authored by Judge Hawkins and joined by Chief Judge Kozinski and Third Circuit Judge Cowen, the Ninth Circuit thoroughly detailed the Complaint allegations it found relevant to support Respondents' loss causation theory, often citing to particular Complaint paragraphs. *Gilead*, 536 F.3d at 1050-54. Because Petitioners challenge the "basis in fact" for the opinion, Respondents' fact summary here tracks the facts as articulated by the Ninth Circuit, supplementing them with additional Complaint citations where helpful because, as the court noted, the Complaint "offers much greater detail." *Id.* at 1050 n.1.

1. *Gilead Artificially Inflated Its Stock Price by Misrepresenting Its True Financial Condition with Concealed Reliance on Off-Label Marketing and Related Wholesaler Stockpiling*

The "fortunes" of Gilead, a biopharmaceutical company, "depended heavily on [the] commercial success" of its key drug, Viread, an antiretroviral agent used to treat patients with HIV. *Id.* at 1050.

"Sales of Viread amounted to about 65% of Gilead's total revenues at all relevant times of this action." *Id.*; *see also* ER 32¶2. "'Wall Street analysts looked to sales of Viread, Gilead's most important and most promoted drug, to gauge whether the Company's business was on track and growing.'" *Gilead*, 536 F.3d at 1050 (quoting ER 32¶4).

Gilead was "required to comply with federal law, including [FDA] marketing regulations," which "prohibit the marketing of drugs for non-FDA-approved uses, commonly referred to as 'off-label' uses." *Id.* at 1050-51. "While physicians are free to prescribe drugs for off-label uses . . . they rely on the FDA-approved prescribing information to determine which drugs can be used safely and effectively by patients with specific health problems." *Id.* at 1051.

"In an October 27, 2003 *Forbes* article, Defendant [Chief Executive Officer John C.] Martin acknowledged that in order for Gilead to reach its goal of increasing new and total prescriptions, it had to convince physicians to switch patients from a competitor's drugs to Gilead's Viread drug regimen." ER 33¶6. Consistent with that goal, "'[i]n order to gain market share, artificially increase perceived demand, and increase sales, Gilead officers, executives, and clinical personnel, with the express knowledge and approval of the [Officers], routinely and consistently provided Gilead's sales and marketing team with off-label information and encouraged, expected, and directed them to use it to sell Viread. . . .'" *Gilead*, 536 F.3d at 1051 (quoting ER 47¶58); *see also* ER 49-56¶¶68-90 (detailing witness reports about Gilead officers arming sales people with off-label studies and non-FDA-reviewed clinical

trials for sole purpose of off-label marketing), ER 68¶139 (explaining that Gilead gave its salespeople off-label slides, posters, and presentation materials to support the illegal, off-label marketing data).

"Viread 'off-label marketing took three forms: (1) marketing to HIV patients co-infected with Hepatitis B; (2) marketing Viread as a first-line or initial therapy for HIV infection; and (3) marketing against Viread's safety profile.'" *Gilead*, 536 F.3d at 1051 (quoting ER 69¶144). "Ultimately, 75%-95% of Viread sales resulted from off-label marketing efforts." *Id.*; *see also* ER 34¶9. The Ninth Circuit found that the Complaint alleges "Gilead misled the investing public by representing that demand for its most popular product was strong without disclosing that unlawful marketing was the cause of that strength." *Gilead*, 536 F.3d at 1050.

On March 14, 2002, Gilead privately received the first of two Warning Letters from the FDA, ordering Gilead to "immediately cease" off-label marketing practices. *Id.* at 1051; *see also* ER 56-57¶¶91-93. "On March 21, 2002, per the FDA's request, Gilead sent a reply that acknowledged receipt of the FDA's letter and agreed to immediately stop off-label marketing." *Gilead*, 536 F.3d at 1051; *see also* ER 57¶94. "This was not done. In fact, Gilead's off-label marketing increased, either at the Officers' direction or with their knowledge and tacit encouragement." *Gilead*, 536 F.3d at 1051; *see also* ER 65¶¶125-27.[5]

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[5] Indeed, Gilead continues to unlawfully rely on off-label marketing to promote its drugs. On February 27, 2009, the FDA again publicly issued a Warning Letter, chastising Gilead for "false or misleading" statements that "minimize[d] the serious risks [potential liver injury and the risk of birth defects] associated with [another Gilead drug]" contrary to

"By June 2003, Gilead's off-label marketing put it in the position to raise Viread's price." *Gilead*, 536 F.3d at 1051. "Consistent with standard industry practice," Gilead pre-announced the price increase to wholesalers who "typically stockpile drugs in advance of price increases so that they can resell at a higher price to retailers after the increase takes effect." *Id.* at 1051-52; *see also* ER 76-77¶¶166-71. "Because Gilead had 'illegally inflated sales and artificially inflated demand for Viread'" through its off-label marketing, wholesalers—who use current sales numbers to predict future demand when stockpiling in anticipation of a price increase—bought "mass quantities of Viread[,] . . . confirming 'the impression that Viread was in high demand and that Gilead's financial and operational results were strong.'" *Gilead*, 536 F.3d at 1052 (quoting ER 77¶¶171-72); *see also* ER 77-78¶173.

On July 14, 2003, the first day of the Class Period,[6] Gilead announced that "its second quarter financial results would exceed analysts' expectations," explaining that "'[t]he main reason for the jump in Viread sales is an increase in prescriptions, not inventory stocking.'" *Gilead*, 536 F.3d at 1052 (quoting ER 79 ¶179); *see also* ER 78-79 ¶¶174-79. "This statement was misleading. It created the impression that demand for Viread was strong, which it was, but for reasons that were not well-understood by the public." *Gilead*, 536 F.3d at 1052.

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the FDA warning label and risk management plan. *See* http://www.fda.gov/cder/warn/2009/Letairis_Letter.pdf.

[6] The class period alleged is July 14, 2003 through October 28, 2003 ("Class Period").

Echoing Fifth Circuit Judge Jones' recognition that "a half-truth is sometimes more misleading than an outright lie" (*Plotkin v. IP Axess Inc.*, 407 F.3d 690, 702 (5th Cir. 2005)), the Ninth Circuit held "[o]mitting the role of off-label marketing in a press release highlighting the drug's success made a true statement (that demand was strong) also a misleading one." *Gilead*, 536 F.3d at 1052. The financial news "had a marked effect on [Gilead's] stock price," causing an overnight 13.4% increase to a "near-record high." *Id.*

2. *Although the FDA Publicly Warned Gilead to Stop Off-Label Marketing, the Public—Unaware of Gilead's Economic Reliance on the Unlawful Practice—Attached Little Significance and the Stock Price Remained Artificially Inflated*

On July 29, 2003, the FDA issued a second warning letter to Gilead, chastising Gilead for off-label marketing at a national HIV/AIDS conference. *Id.* The FDA letter stated that Gilead's illegal acts were "particularly troubling because the more than 1,500 attendees of [the 15th National HIV/AIDS Update Conference] included social workers, AIDS educators, and patients with HIV/AIDS, and you had previously been warned not to engage in such activities." ER 65¶127, ER 106. The FDA letter "expressed the 'significant public health and safety concerns raised by these repetitive promotional activities.'" *Gilead*, 536 F.3d at 1053 (quoting ER 109). The FDA made the letter public on August 7, 2003. *Id.*

"Gilead's shareholders and the investing public did not find [the FDA letter] very significant, though, because they failed to appreciate the extent of Gilead's off-label marketing, and thus could not foresee the letter's impact on Viread's sales." *Id.*; *see also* ER 82-83¶¶191-95. The public's lack of understanding of the significance of the letter was reflected in the fact that "shares closed at higher prices than they opened on both August 7 and August 8." *Gilead*, 536 F.3d at 1053.

"Yet, '[u]nbeknownst to investors, the disclosure of the FDA Warning Letter had a detrimental effect on Viread sales. . . .'" *Id.* (quoting ER 85¶200). "'Physicians, now alerted to Gilead's illegal marketing efforts and to the safety problems with Viread, were less eager to prescribe it to their patients.'" *Id.* "Competitors invoked the letter in efforts to persuade physicians to switch from Viread to their products." *Id.* Thus, the FDA letter caused a "'marked drop in prescriptions and sales'" of Viread. *Id.* (quoting ER 85¶201). "Although the Investors lack precise sales figures, a Morgan Stanley analyst report [issued October 29, 2003] shows that Viread prescriptions experienced a 'sharp drop' in August 2003, followed by 'flattened growth' for the remainder of the third quarter." *Id.*

Indeed, the Ninth Circuit agreed that "[i]t is not unreasonable that physicians—the targets of the off-label marketing—would respond to the Warning Letter while the public failed to appreciate its significance." *Id.* at 1058. "The prescriptions would have suffered further decline were it not for certain side-effects that made it dangerous for some patients to discontinue using the drug." *Id.* at 1053; *see also* ER 58-59¶100, 86¶202.

Wholesalers "observed the initial drop in sales and prescriptions of Viread, and the ensuing slow growth." *Gilead*, 536 F.3d at 1053; *see also* ER 86 ¶204. They drew down their "supply of Viread . . . to the lowest level in four quarters, and well below the industry average for other drugs." *Id.*

The market, however, "continued to misunderstand the significance of the Warning Letter." *Gilead*, 536 F.3d at 1053; *see also* ER 83¶195. Gilead continued to conceal "the activities that gave rise to that letter, or the impact the letter would have on sales of Viread." *Gilead*, 536 F.3d at 1053. The Ninth Circuit agreed that "[t]he Warning Letter, which discussed only two instances of off-label marketing, would not necessarily trigger a market reaction because it did not contain enough information to significantly undermine Gilead's July 2003 pronouncements concerning demand for Viread." *Id.* at 1058.

"The Officers exploited the public's ignorance." *Id.* at 1053. Between the date the FDA letter was issued to Gilead and the date that it was made public, two Gilead officers each sold over $3 million in Gilead stock—with a third officer selling nearly $700,000 worth of shares on the day the letter was publicly disclosed. *Id.* "Throughout August, while the market misapprehended Gilead's impending troubles, the Officers continued to sell off substantial numbers of shares" in a manner that was "unusual and suspicious." *Id.* at 1053-54.

3. *When Gilead Admitted Decreased Quarterly Earnings on October 28, 2003, Investors Learned the Economic Impact of the Off-Label Marketing and Related Wholesaler Overstocking—and Gilead's Stock Price Immediately Declined 12%*

"Not until October 28, 2003, did the public finally realize the impact of the off-label marketing and the Warning Letter." *Id.* at 1054; *see also* ER 86-87¶205. After the market closed, Gilead revealed that its third quarter financial results "fell significantly below expectations." *Gilead*, 536 F.3d at 1054; *see also* ER 85-87 ¶¶200-05. Gilead blamed wholesaler overstocking. *Id.* "Market analysts attributed the disappointing sales to 'lower end-user demand.'" *Id.* "That lower end-user demand, as noted, was a direct result of the Warning Letter, which had exposed Gilead's unlawful off-label marketing efforts to physicians." *Id.* In short, Gilead's disclosure of its third-quarter financial results "made the effect of [Gilead's off-label marketing] inescapably clear." *Id.*

The following day, trading volume for Gilead was "up 1,400% from its average daily level." *Gilead*, 536 F.3d at 1054; *see also* ER 87-88 ¶208. The stock price dropped 12% in one day. *Id.* "Importantly, the drop occurred immediately after Gilead disclosed less-than-expected revenues resulting from the reduction in wholesalers' Viread inventories, which analysts ascribed to lower end-user demand. That lower end-user demand, in turn, is expressly alleged to have been caused by the Warning Letter." *Gilead*, 536 F.3d at 1058. Thus, "the market did react immediately to the corrective disclosure—the October 28 press release." *Id.*

B. Prior Rulings by District Court

The district court held "Plaintiffs have adequately alleged that Defendants engaged in an illegal off-label marketing scheme." ER 25. In fact, the court twice held "Plaintiffs have alleged sufficient facts to raise a strong inference that Defendants had knowledge of the company's off-label marketing scheme." ER 12, 25.

The court understood and acknowledged Respondents' claim regarding the impact of that fraud: "According to Plaintiffs, Defendants' off-label marketing enabled the company to create the appearance of increased prescriptions and demand for Viread." ER 11. The court understood that "[a]s a result, wholesalers [who estimate future demand by reviewing past sales] were encouraged to stock up on Viread ahead of Gilead's announced price increase." *Id.* The court stated "Plaintiffs further allege that Gilead's second quarter sales estimates, including wholesaler stocking, were tainted by the off-label marketing scheme because the marketing 'created an artificial and illusory demand for Viread.'" *Id.*

The court also understood and articulated Respondents' theory of loss causation. ER 136-37. Summarizing, the court explained that "it was [a] foreseeable, very significant risk, that if they engage in off label[] marketing techniques to the degree that's alleged, it was foreseeable at some point that this house built on quick sand would fall and the numbers would be what they assert." *Id.* The court concluded: "that is the theory, if I am right." *Id.*

The district court erred, however, by disbelieving Respondents' theory at the pleading stage. The court picked evidentiary holes in Respondents' loss cau-

sation theory and rejected it on the purported strength of those holes:

> There are too many logical and factual gaps in Plaintiffs' allegations to support the conclusion that Defendants' alleged misconduct proximately caused Gilead's stock decrease in October. . . . The [Complaint] does not connect the following chain of events, which it must for Plaintiffs to adequately plead loss causation: 1) that Defendants' alleged failure to disclose the off-label marketing scheme caused a material increase in sales; 2) that practitioners materially decreased their demand for Viread due to the publication of the FDA Warning Letter; and most importantly; 3) that the alleged decrease in sales due to the FDA letter proximately caused Gilead's stock to decrease three months later.

ER 183 n.12.

C. Ninth Circuit Decision, Applying this Court's Pleading Standard

Correctly applying *Dura*, the Ninth Circuit reversed the district court's order of dismissal. "Our review of the Investors' complaint convinces us that the October drop in stock price was plausibly caused by the Warning Letter." *Gilead*, 536 F.3d at 1058.

Initially, the Ninth Circuit recognized that "[a] plaintiff bears the burden of proving that a defendant's alleged unlawful act 'caused the loss for which the plaintiff seeks to recover damages.'" *Id.* at 1055 (quoting 15 U.S.C. §78u-4(b)(4)). "To establish loss causation, the plaintiff must demonstrate a causal connection between the deceptive acts that form the basis for the claim of securities fraud and the injury suffered by the plaintiff." *Id.*

"The misrepresentation need not be the sole reason for the decline in value of the securities, but it must be a 'substantial cause.'" *Id.* (quoting *Robbins v. Koger Props., Inc.*, 116 F.3d 1441, 1447 n.5 (11th Cir. 1997)).

Acknowledging the parties' dispute about the relevant pleading standard, the Ninth Circuit held it "need not resolve" whether loss causation must be pled to satisfy Rule 8 or Rule 9 because this Complaint satisfied both standards. *Id.* at 1056. The Ninth Circuit more than met *Dura*'s demand for "some indication of the loss and the causal connection that the plaintiff has in mind" (544 U.S. at 347), requiring "some assurance that the theory has a basis in fact." *Gilead*, 536 F.3d at 1056. "Therefore, under either Rule 8 or Rule 9, the Investors have sufficiently pleaded loss causation." *Id.*

The Ninth Circuit thoroughly analyzed *Dura*, concluding the facts alleged here are "meaningfully different." *Id.* "The Investors here identify a specific economic loss: the drop in value on October 29, 2003, that followed the October 28 press release." *Id.* "They also allege that this loss was caused by Gilead's misrepresentations." *Id.* "They provide abundant details of Gilead's off-label marketing, and they assert that this led to higher demand for Viread, which in turn inflated Gilead's stock price." *Id.*

Further, the Ninth Circuit held that, in pleading the facts that caused that inflation to come out of the stock price, the "complaint *specifically* alleges that physicians were less eager to prescribe Viread, and competitors used the Warning Letter to lure Viread customers to other drugs." *Id.* at 1058. The Ninth Circuit concluded "[i]t is not unreasonable that physicians—the targets of the off-label marketing—

would respond to the Warning Letter while the public failed to appreciate its significance." *Id.*

"[W]e find the complaint sufficiently alleges a causal relationship between (1) the increase in sales resulting from the off-label marketing, (2) the Warning Letter's effect on Viread orders, and (3) the Warning Letter's effect on Gilead's stock price." *Id.* at 1057. The specific allegations are "enough fact to raise a reasonable expectation that discovery will reveal evidence – or the lack thereof – of the Warning Letter's effect on demand." *Id.* at 1058.

III. REASONS FOR DENYING THE PETITION

A. Certiorari Is Unwarranted Because the "2-3-1 Split" Among the Circuits Asserted by Petitioners Does Not Exist; There Is No Split Among the Circuits

There is no split among the circuits regarding the standard for pleading loss causation. Indeed, all circuits addressing the issue—including the Ninth Circuit here—use remarkably similar language in describing the pleading standard. Faithfully following this Court's clear guidance in *Dura*, circuit courts around the country require a theory of loss causation with enough facts to assure its plausibility. There is no need for this Court to revisit this issue.

In *Dura*, this Court held that to plead loss causation, a plaintiff "must provide the defendant with fair notice of what the plaintiff's claim is and the grounds upon which it rests." 544 U.S. at 346. Striking a balance between preventing "abusive practices including the routine filing of lawsuits . . . with only a faint hope that the discovery process might lead eventually to some plausible cause of action" and honoring long-standing principles of

federal pleading which are "not meant to impose a great burden upon a plaintiff," this Court expressly identified the level of assurance necessary for loss causation allegations in a securities fraud claim to survive the pleading stage: allegations that provide "a reasonably founded hope that the [discovery] process will reveal relevant evidence." *Id.* at 347.

The Ninth Circuit required exactly that: "Investors' complaint offers sufficient detail to give defendants ample notice of [Investors'] loss causation theory [mirroring "fair notice of what the plaintiff's claim is"], and to give us some assurance that the theory has a basis in fact [mirroring "the grounds upon which it rests"]." *Compare Gilead*, 536 F.3d at 1056 *with Dura*, 544 U.S. at 347. Mirroring this Court's "reasonably founded" language, the Ninth Circuit concluded that Respondents' Complaint provided "enough fact to raise a reasonable expectation that discovery will reveal evidence—or the lack thereof—of the Warning Letter's effect on demand." *Compare Gilead*, 536 F.3d at 1058 *with Dura*, 544 U.S. at 347.

Moreover, the Ninth Circuit's upholding of complaint allegations that "plausibly establish loss causation" follows this Court's proscription of the opposite: claims "with only a faint hope that the discovery process might lead eventually to some plausible cause of action." *Compare Gilead*, 536 F.3d at 1057 *with Dura*, 544 U.S. at 347. In this case, the Ninth Circuit found the loss causation allegations "plausible" and held that there was a "reasonable expectation" that discovery would reveal evidence to support the allegations. That is precisely the standard for pleading loss causation outlined by this Court in *Dura*.

Other circuits require similar allegations. Shortly before this Court's decision in *Dura*, the Second Circuit held that "[t]o plead loss causation, the complaint must allege facts that support an inference that [the company's] misstatements and omissions concealed the circumstances that bear upon the loss . . . ." *Lentell v. Merrill Lynch & Co. Inc.*, 396 F.3d 161, 174 (2d Cir. 2005). The court required a theory and some supporting facts.

Importantly, the Second Circuit makes absolutely clear that the revelation of negative economic news need not precisely match the alleged prior misstatement or omission for loss causation allegations to survive the pleading (or proof) stage. *Id.* at 173. Rather, loss causation allegations are sufficient if they allege that the loss was "foreseeable" and "caused by the materialization of the concealed risk." *Id.* (referencing *Suez Equity Investors, L.P. v. Toronto-Dominion Bank*, 250 F.3d 87, 95 (2d Cir. 2001)). By way of example, the Second Circuit cites allegations that an executive's "concealed lack of skill would cause the company's eventual liquidity problems" as sufficient to plead the "causal precursor" to the loss. *Id.* at 174. Thus, revelation of the liquidity problems would trigger the loss caused by the concealment of the executive's lack of skill—loss need not necessarily be triggered by an admission or direct revelation of the previously concealed lack of skill of the executive. *Id.*

The Second Circuit's analysis follows this Court's guidance that there is "more than one way to demonstrate the causal connection . . . between the plaintiffs' injury and the defendant's wrongful conduct" in a Rule 10b-5 cause of action. *Basic Inc. v. Levinson*,

485 U.S. 224, 243 (1988). Loss causation allegations need not be limited to defendants' public confessions.

Since *Dura*, the Second Circuit (with Justice O'Connor sitting) has continued to follow *Lentell*, focusing on tort law concepts of foreseeability, a plausible theory and some related factual support, holding that "[a] misstatement is the proximate cause of an investment loss if the risk that caused the loss was within the zone of risk concealed by the misrepresentations . . . alleged. . . ." *Lattanzio v. Deloitte & Touche LLP*, 476 F.3d 147, 157 (2d Cir. 2007). Thus, the Second Circuit requires securities fraud plaintiffs to articulate a theory of loss causation—in *Lattanzio*, "that Deloitte's misstatements concealed the risk of Warnaco's bankruptcy." *Id.* *Lattanzio* simply concluded plaintiffs did not plausibly articulate that theory because the complaint alleged the risk of bankruptcy had already been disclosed. *Id.* at 158. In other words, plaintiffs' loss causation theory was not plausible.

The Fourth Circuit follows suit. Like the Ninth Circuit here, the Fourth Circuit refrained from choosing between Rule 8 and Rule 9 pleading standards, simply holding a securities fraud plaintiff must plead loss causation "with sufficient specificity to enable the court to evaluate whether the necessary causal link exists." *Compare Teachers' Ret. Sys. v. Hunter*, 477 F.3d 162, 186 (4th Cir. 2007) *with Gilead*, 536 F.3d at 1056 ("sufficient detail . . . to give us some assurance that the theory has a basis in fact"). The Fourth Circuit acknowledged that "[l]oss causation is not one of the elements with respect to which the PSLRA imposes a more stringent pleading requirement" and the dissent explicitly stated that loss causation "is not subject to any heightened pleading

requirement under the PSLRA." *Teachers' Ret.*, 477 F.3d at 185, 194. Moreover, in analyzing loss causation, the Fourth Circuit referenced *Lentell*, underscoring the uniformity among the circuits. *Id.* at 186. Like *Lattanzio*, *Teachers' Ret.* simply held "[t]he problem with plaintiffs' theory . . . is that these facts had already been disclosed in public filings . . . ." *Id.* at 187. No "new facts" were disclosed "that revealed [the company's] previous representations to have been fraudulent." *Id.* The loss causation theory was not plausible.

As noted above, the Ninth Circuit applied the same standard, concluding plaintiffs' theory *was* plausible. *Gilead*, 536 F.3d at 1058 ("It is not unreasonable that physicians—the targets of the off-label marketing—would respond to the Warning Letter while the public failed to appreciate its significance."). Thus, although certain information—the Warning Letter—was publicly revealed, the economic impact of off-label marketing on Viread's sales remained concealed until October 28, 2003. *Id.* ("Importantly, the drop occurred immediately after Gilead disclosed less-than-expected revenues resulting from the reduction in wholesalers' Viread inventories, which analysts ascribed to lower end-user demand. That lower end-user demand, in turn, is expressly alleged to have been caused by the Warning Letter."). The court found a plausible theory with a factual basis.

Similarly, the Eighth Circuit requires a loss causation theory with some facts to assure its plausibility. *Schaaf v. Residential Funding Corp.*, 517 F.3d 544, 550 (D. Minn.), *cert. denied*, 129 S. Ct. 222 (2008) (citing *Lentell*, 396 F.3d at 173). Again, *Schaaf* affirmed dismissal because the complaint allegations showed plaintiffs' loss causation theory was

not plausible. *Id.* at 553. As this Court recently held in *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 556 (2007), even under Rule 8 pleading standards, a complaint must allege "enough factual matter (taken as true) to suggest . . . plausible grounds" for plaintiffs' claim. Noting the parallels to *Dura*, *Bell Atlantic* "simply calls for enough fact to raise a reasonable expectation that discovery will reveal evidence of" the claim. *Bell Atl.*, 550 U.S. at 556, 563 n.8.

Thus, the circuits are in harmony. Struggling to create a "split," Petitioners cite to one word in an unpublished decision by the Fifth Circuit which can hardly be said to articulate that circuit's application of *Dura*. *Catogas v. Cyberonics, Inc.*, 292 F. App'x 311 (5th Cir. 2008). The Fifth Circuit applied the same plausible theory test applied by every other circuit, concluding the loss causation theory was not plausible because the alleged corrective revelation "did not reveal anything regarding the accounting of options that had not already been disclosed to the investing public." *Id.* at 315. The Fifth Circuit did not hold that Rule 9 applies to loss causation—nor did the court undertake any analysis on that issue. *Id.* at 314-15. Indeed, Judge Higginbotham, on the *Catogas* panel, previously authored an opinion for the Fifth Circuit, holding the Private Securities Litigation Reform Act ("PSLRA") requires particularity only as to "time, place and contents of the false representations, as well as the identity of the person making the misrepresentation and what [that person] obtained thereby." *Williams v. WMX Techs., Inc.*, 112 F.3d 175, 177-78 (5th Cir. 1997). The later unpublished decision in *Catogas* simply follows this Court's direction for "sufficient allegations that the misrepresentations caused plaintiffs' loss." 292 F. App'x at 314 (citing *Dura*, 544 U.S. at 343). Petitioners' assertion of a

"split" in the circuits hinges on the word "particularity" in the introductory paragraph of an unpublished decision, overlooking the Fifth Circuit's published decision in *Williams*. *Id.* at 312.

Petitioners' contrary assertion notwithstanding, the Seventh Circuit also follows this Court's guidance, requiring "a causal connection between the material misrepresentation and the loss . . . when the facts . . . become *generally known*." *Tricontinental Indus. v. PricewaterhouseCoopers, LLP*, 475 F.3d 824, 843 (7th Cir.) ("In the present case, therefore, Tricontinental had to allege that PwC's 1997 audit contained a material misrepresentation which caused Tricontinental to suffer a loss when that material misrepresentation 'became *generally known*.'"), *cert. denied*, 128 S. Ct. 357 (2007).

The Seventh Circuit did not hold Rule 9 applies to loss causation. Indeed, the court held to the contrary—that Rule 9 applies to "the circumstances constituting fraud . . . the who, what, when, where, and how . . . ." *Id.* at 833. The Seventh Circuit recognized "[t]his heightened pleading requirement does not extend to states of mind" and the court did not even deem it necessary to mention loss causation in this context. *Id.* Consistently, Judge Posner has previously written for the Seventh Circuit, holding Rule 9 requires particularity only as to "the who, what, where, and when of the alleged fraud." *Ackerman v. Northwestern Mutual Life Ins. Co.*, 172 F.3d 467, 469 (7th Cir. 1999). Nothing in *Tricontinental* states the dismissal was affirmed because of a lack of particularity in pleading loss causation. Rather, the Seventh Circuit held the loss causation theory *implausible* in light of the complaint allegations: "Tricontinental, however, has not

identified any statements by Anicom or PwC that made '*generally known*' any problems or irregularities in the 1997 audited financial statement." 475 F.3d at 843. The complaint linked plaintiffs' loss to statements in 1998 and 1999 financial statements—not the 1997 financial statements which plaintiffs alleged were fraudulent. *Id.* at 843-44.

As in *Catogas*, the substantive Rule 10b-5 loss causation analysis in *Tricontinental* does not discuss Rule 9. *Id.* Indeed, by repeatedly requiring that the truth become "generally known," the Seventh Circuit follows this Court's guidance and falls in line with every other circuit that has addressed the issue, requiring a plausible theory and some facts to support it. Petitioners rely on peripheral language in a footnote in a separate section of the opinion which states only that the state law "negligent misrepresentation claim must be evaluated according to the pleading requirements of Rule 8, not the heightened pleading requirements of Rule 9" and that the negligent misrepresentation claim does allege loss causation. *Id.* at 839 n.10. In the context of *Tricontinental*'s earlier Rule 9 discussion—limited to "the circumstances constituting fraud" (*id.* at 833)—and the court's prior decision in *Ackerman*, this footnote is ambiguous. In any event, it is hardly a developed analysis—and certainly not a basis for suggesting a split among the circuits.

The Tenth Circuit recently confirmed the logic followed by all the above circuits: loss causation must be pled with a plausible theory and some factual support. "Any reliable theory of loss causation that uses corrective disclosures will have to show both that corrective information was revealed and that this revelation caused the resulting decline in price."

In re Williams Sec. Litig.-WCG Subclass, ___ F.3d ___, No. 07-5119, 2009 WL 388048, at *8 (10th Cir. Feb. 18, 2009). Even at summary judgment, the Tenth Circuit held "[t]o be corrective, the disclosure need not precisely mirror the earlier misrepresentation." *Id.* Instead, "it must at least relate back to the misrepresentation and not to some other negative information about the company." *Id.* Importantly, the Tenth Circuit emphasized "if we are too exacting in our demands for a connection between the initial misrepresentation and the subsequent revelation—for instance, by imposing a mirror image requirement . . . then we would eliminate the possibility of 10b-5 claims altogether." *Id.*

This Court's guidance is clear. There is no split in the circuits. The Petition should be denied.

B. Certiorari Is Unwarranted Because the Test Articulated by This Court in *Dura*—"Fair Notice of What the Plaintiff's Claim Is and the Grounds Upon Which It Rests"—Is Precisely the Standard Applied by the Ninth Circuit—"Sufficient Detail to Give Defendants Ample Notice of [Investors'] Loss Causation Theory, and to Give Us Some Assurance that the Theory Has a Basis in Fact"

The Ninth Circuit applied the pleading standard for loss causation articulated in *Dura* and followed by every circuit in the country that has addressed the issue: a theory of loss causation with some facts to assure its plausibility. Petitioners seek to expand *Dura* to require evidentiary specifics well beyond

what *Dura* contemplates. Certiorari should be denied.

1. *The Ninth Circuit Explicitly Held Investors Alleged Loss Causation Sufficiently to Satisfy "Either Rule 8 or Rule 9" and Demanded More than Rule 8 Notice by Requiring a "Basis in Fact" Under Rule 9*

The Ninth Circuit held that "under either Rule 8 or Rule 9, the Investors have sufficiently pleaded loss causation." *Gilead*, 536 F.3d at 1056. Despite Petitioners' insistence that the Ninth Circuit either does not understand Rule 9 or was disingenuous in applying it, the opinion scrupulously marshals the "basis in fact" supporting Respondents' loss causation theory. *Id.* at 1050-54. Taking almost five full pages to recount the factual basis for Respondents' loss causation theory, the Ninth Circuit concluded "Investors did in fact explicate the causal logic underlying their theory." *Id.* at 1050 n.1. The court noted the Complaint contains "much greater detail" than contained in the five pages (*id.*) and held there was "sufficient detail" to provide "some assurance that the [loss causation] theory has a basis in fact." *Id.* at 1056. In particular, the Ninth Circuit held the Complaint "specifically alleges that physicians were less eager to prescribe Viread, and competitors used the Warning Letter to lure Viread customers to other drugs." *Id.* at 1058.

The Petition mischaracterizes the Ninth Circuit's opinion. Overlooking the Ninth Circuit's holding that it found "sufficient detail" in the Complaint to be assured Respondents' loss causation theory has a "basis in fact" (*id.* at 1056), Petitioners (incorrectly)

assert the "Ninth Circuit has required no factual basis." Pet. 20. Summarizing other circuits' decisions which also required some assurance of a factual basis for a loss causation theory, the Petition (inaccurately) declares "the Ninth Circuit permits a complaint devoid of such factual allegations to survive." Pet. 24. Despite the Ninth Circuit's clear language to the contrary and its copious citation to "specific[]" factual allegations (*e.g.*, *Gilead*, 536 F.3d at 1058), the Petition states the Ninth Circuit "holds that factual specificity is not required." Pet. 17.

The text of the opinion speaks for itself. The Ninth Circuit recounted the Complaint's factual allegations. *Gilead*, 536 F.3d 1050-54. Moreover, the Ninth Circuit did indeed analyze Respondents' loss causation allegations under both Rule 8 and Rule 9, concluding the factual allegations are sufficient under either standard. *Id.* at 1056. Carefully following *Dura*, the Ninth Circuit found "enough fact to raise a reasonable expectation that discovery will reveal evidence – or the lack thereof – of the Warning Letter's effect on demand." *Id.* at 1058.

2. *Petitioners Now Seek to Broaden Dura to Require Evidentiary Specifics Not Contemplated by This Court*

Strikingly, the Petition articulates Respondents' theory of loss causation: Gilead's October 28, 2003 announcement that third-quarter Viread revenues had declined "was perceived by the market as negative news, as it meant that the true demand for Viread (reflecting the number of patients actually using the drug) going into the third quarter had been less than previously believed." Pet. 8-9.

Petitioners further acknowledge the factual basis for Respondents' theory by disputing the facts. Thus, while the Ninth Circuit held a "slowing increase in demand"—demonstrated by an analyst report attached to the Complaint—was sufficient to "proceed to the evidentiary stages to determine the extent of the Warning Letter's impact on the growth of demand for Viread" (*Gilead*, 536 F.3d at 1058), Petitioners reprise the arguments they made in the district court and to the Ninth Circuit that slower growth is still growth. Pet. 13-14. Petitioners' assertion must await trial.

Petitioners want evidentiary proof—even beyond the analyst report attached to the Complaint here. In making this assertion, Petitioners push well past what this Court required in *Dura*, where this Court held that plaintiffs need only provide a short, plain statement that "provides the defendants with notice of what the relevant economic loss might be or of what the causal connection might be between that loss and the misrepresentation" alleged in the complaint. 544 U.S. at 347. This Court held that complying with this standard is "not meant to impose a great burden upon a plaintiff." *Id.* Rather, plaintiff need only allege that the "relevant truth" concealed by the alleged fraud was disclosed to the market, causing a decline in the price of publicly traded securities that damaged investors, including the plaintiff. *Id.*

As referenced above, the issue of the applicable pleading standard arose at oral argument in *Dura*. 2005 U.S. TRANS LEXIS 4, at *19-*27. Justice Ginsburg explicitly rejected defendants' assertion that Rule 9(b) pleading standards should apply to loss causation: "I thought you pointed to the 9(b)

pleading rule because fraud must be pleaded with particularity, but causation does not, not under the rules and not under the statute." *Id.* at *19. When defendants insisted that heightened pleading standards should apply because loss causation is an element of fraud, Justice Ginsburg again rejected the assertion: "[N]o. It said fraud must be pleaded with particularity, not all the elements of a fraud claim." *Id.* Indeed, Rule 9 requires only that "the circumstances constituting fraud or mistake" be stated with particularity. Justice Breyer explicitly articulated that pleading loss causation was a simple matter of alleging "what your theory is." *Id.* at *26. "Nobody is asking for some facts. . . . All they're asking is not for evidence, but a simple, clear explanation of the theory . . . ." *Id.* at *26-*27.

While Petitioners assert – without support – that Rule 9 should also apply to pleading loss causation, the plain text of the PSLRA defeats their assertion. The PSLRA requires particularized pleading of falsity and allegations that sum to a "strong inference" of scienter. 15 U.S.C. §78u-4(b)(1)-(2). But, the PSLRA imposes no heightened pleading requirement for loss causation. *Id.*; *see Gebhardt v. ConAgra Foods, Inc.*, 335 F.3d 824, 830 n.3 (8th Cir. 2003) (PSLRA "does not change traditional pleading rules with respect to . . . materiality and loss causation"); *accord Williams*, 112 F.3d at 177-78 (PSLRA requires particularity only as to "time, place and contents of the false representations, as well as the identity of the person making the misrepresentation and what [that person] obtained thereby"); *In re Lord Abbett Mut. Funds Fee Litig.*, 553 F.3d 248, 250 n.2 (3d Cir. 2009) (PSLRA's heightened pleading requirement applies only to falsity and scienter).

Because the PSLRA explicitly heightens the pleading requirement for falsity and scienter—but is silent as to pleading loss causation—this Court presumes Congress acted intentionally. "Where Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion." *Gozlon-Peretz v. United States*, 498 U.S. 395, 404 (1991). Had Congress meant to increase the pleading requirements for loss causation, it surely would have said so: "*Expressio unius est exclusio alterius.*" *Leatherman v. Tarrant County Narcotics Intelligence & Coordination Unit*, 507 U.S. 163, 168 (1993).

Petitioners themselves reference this very principle of statutory construction. Pet. 18 n.5. But, Petitioners rely on the absence of discussion about loss causation in Rule 9—ignoring the *subsequent* PSLRA's discussion of heightened pleading requirements for certain elements, other than loss causation.

"In this era of corporate scandal, when insiders manipulate the market with the complicity of lawyers and accountants, we are cautious not to raise the bar of the PSLRA any higher than that which is required under its mandates." *No. 84 Employer-Teamster Joint Council Pension Trust Fund v. America West Holding Corp.*, 320 F.3d 920, 946 (9th Cir. 2003). The PSLRA "was not enacted to raise the pleading burdens under Rule 9(b) and section 78u-4(b)(1) to such a level that facially valid claims, which are not brought for nuisance value or as leverage to obtain a favorable or inflated settlement, must be routinely dismissed on Rule 9(b) and 12(b)(6) motions." *ABC Arbitrage Plaintiffs Group v. Tchuruk*, 291 F.3d 336,

354 (5th Cir. 2002) (Higginbotham, J.). "Nothing in the Act . . . casts doubt on the conclusion 'that private securities litigation [i]s an indispensable tool with which defrauded investors can recover their losses' – a matter crucial to the integrity of domestic capital markets." *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 127 S. Ct. 2499, 2508 n.4 (2007).

Thus, as this Court assumed in *Dura*, "neither the Rules [of Civil Procedure] nor the securities statutes impose any special further requirement in respect to the pleading of proximate causation or economic loss." 544 U.S. at 346. Rather, the fact that all circuits addressing the issue require a theory with some factual basis simply acknowledges the overlap of pleading standards under Rules 8 and 9. *See United States ex rel. v. Martin-Baker Aircraft Co.*, 389 F.3d 1251, 1256 (D.C. Cir. 2004). Even under a Rule 8 standard – which applies to loss causation—this Court holds that "a plaintiff's obligation to provide the 'grounds' of his 'entitle[ment] to relief' requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Bell Atl.*, 550 U.S. at 555. There must be "enough factual matter (taken as true) to suggest" a claim. *Id.* at 556. Following this Court's guidance, the Ninth Circuit held "[s]o long as the complaint alleges facts that, if taken as true, plausibly establish loss causation, a Rule 12(b)(6) dismissal is inappropriate." *Gilead*, 536 F.3d at 1057.

Importantly, however, "[t]his is not 'a probability requirement.'" *Id.* (quoting *Bell Atl.*, 550 U.S. at 556). "'[I]t simply calls for enough fact to raise a reasonable expectation that discovery will reveal evidence of' loss causation." *Id.* The Ninth Circuit concluded that Respondents' Complaint alleges "enough fact to raise

a reasonable expectation that discovery will reveal evidence—or the lack thereof—of the Warning Letter's effect on demand." *Gilead*, 536 F.3d at 1058 (quoting *Bell Atl.*, 550 U.S. at 556).

Petitioners' demand for more than a plausible theory with a factual basis has no support. The Petition should be denied.

3. *Petitioners Inappropriately Request that This Court Revisit the Fact-Bound Arguments Which the Ninth Circuit Properly Rejected Under* Dura

Careful reading of the Petition exposes Petitioners' true goal: factual rehearing of the Ninth Circuit's conclusion that Respondents' theory is plausible. They raise the same fact-bound assertions they raised below—all of which were carefully considered and rejected by the Ninth Circuit. Petitioners' request for rehearing is not a proper basis for certiorari.

For example, Petitioners assert—as they did below—that the decline in Viread prescriptions in the third quarter was "attributed . . . to wholesaler inventory stocking," representing that the conclusion is found in a "Morgan Stanley analyst report." Pet. 13, citing ER 114-15. But, the Morgan Stanley analyst report referenced states that—even after accounting for inventory stocking—demand for Viread was down. "[N]ormalized for inventory build/ drawdown, currency, and price increases," the "underlying demand growth" in the third quarter was 10% as compared with 21% in the second quarter and 22% in the first. ER 117. Thus, according to Morgan Stanley, Viread's demand growth curve took a serious dip in the third quarter of 2003. ER 115 ("The only

lingering fundamental factor among the aforementioned is the fact that end-user demand run rates were actually lower than previously believed."). As the Ninth Circuit held, there is "no reason why the court cannot proceed to the evidentiary stages to determine the extent of the Warning Letter's impact on the growth of demand for Viread." *Gilead*, 536 F.3d at 1058.

Similarly reiterating a factual assertion made—and rejected—below, the Petition attempts to defeat loss causation allegations at the pleading stage because Gilead's "stock recovered nearly half that loss within one day and recovered fully within a month." Pet. 9. But, Petitioners' pleas that the eventual stock price recovery somehow negates the loss caused by the stock price drop were anticipated and rejected by the PSLRA which provides a method for calculating the stock price "bounce back." Under the PSLRA's established 90-day "bounce back" provision, an award of damages is limited to the difference between an investor's purchase price and "the mean trading price of that security during the 90-day period beginning on the date on which the information correcting the misstatement or omission that is the basis for the action is disseminated to the market." 15 U.S.C. §78u-4(e)(1). Applying that provision, Petitioners are liable for substantial damages—at least tens of millions of dollars—to the Class. No other analysis is necessary. Respondents are not required to *prove* the amount of their damages at the pleading stage. *Gebhardt*, 335 F.3d at 832 (In ruling on a motion to dismiss, "we decline to attach dispositive significance to the stock's price movements absent sufficient facts and expert testimony, which cannot be considered at this procedural juncture, to put this information in its proper context.").

The essence of Respondents' Complaint is that Petitioners concealed known safety concerns and promoted their drug for unapproved uses, exploiting an incredibly vulnerable, life-threatened population to increase sales, boost Gilead's stock price, and cash in on insider sales—and did so in flagrant violation of FDA rules. ER 31-36 ¶¶1-16. Loss causation is amply alleged in "sufficient detail to give defendants ample notice of [Respondents'] loss causation theory, and to give [the Ninth Circuit] some assurance that the theory has a basis in fact." *Gilead*, 536 F.3d at 1056. The Petition should be denied.

4. *Circuits Uniformly Agree that an Alleged Misrepresentation Need Not Be the Sole Reason for the Decline in Value of a Security—as Long as It Is Alleged to Have Been a "Substantial Cause" of the Loss*

Apparently recognizing certiorari is not necessary on the issue of the loss causation pleading standard, Petitioners also request that this Court revisit the settled law that causation is not appropriately apportioned at the pleading stage, representing it as the "second part of *Dura*'s loss causation test." Pet. 24. As a preliminary matter, this issue is not properly considered as it is not subsumed in the Petition's Question Presented. Supreme Court Rule 14. Moreover, it is surprising that Petitioners would raise this as an issue worthy of this Court's attention since their brief advised the Ninth Circuit that the district court's analysis of causation apportionment was "not necessary to its decision." Petitioners' Ninth Circuit Answering Brief at 52 n.14. In any event, this Court has already held that proximate cause means substantial cause—not exclusive cause—

and all circuits that have faced the issue agree district courts should not apportion causation at the pleading stage. Thus, there is no need for this Court's further guidance.

This Court holds "[p]roximate cause is causation substantial enough and close enough to the harm to be recognized by law, but a given proximate cause need not be, and frequently is not, the exclusive proximate cause of harm." *Sosa v. Alvarez-Machain*, 542 U.S. 692, 704 (2004). "'[I]n the ordinary case there may be *several* points along the chain of causality' pertinent to the enquiry." *Id.* (quoting *Beattie v. United States*, 756 F.2d 91, 121 (D.C. Cir. 1984) (Scalia, J., dissenting) (emphasis in original)).

Accordingly, consistent with circuits throughout the country, the Ninth Circuit held here that "[t]he misrepresentation need not be the sole reason for the decline in value of the securities, but it must be a 'substantial cause.'" *Gilead*, 536 F.3d at 1055 (quoting *Robbins*, 116 F.3d at 1447 n.5).

The Third Circuit concurs: "[s]o long as the alleged misrepresentations were a substantial cause of the inflation in the price of a security and in its subsequent decline in value, other contributing forces will not bar recovery. . . ." *Semerenko v. Cendant Corp.*, 223 F.3d 165, 186-87 (3d Cir. 2000). That court noted "defendants may *disprove* that the Class suffered a loss as a result of the alleged misrepresentations by showing that the misrepresentations were not a substantial factor in setting the price of ABI common stock during the Class period," but held that "we disagree that the defendants may do so at this stage of the proceedings." *Id.* at 187; *accord Miller v. Asensio & Co.*, 364 F.3d 223, 229 (4th Cir. 2004).

The Seventh Circuit also finds loss causation amply pled even when a plaintiff's "alleged injuries equally could have been caused by [other] factors." *Caremark, Inc. v. Coram Healthcare Corp.*, 113 F.3d 645, 649 (7th Cir. 1997). Where the plaintiff "alleged a plausible theory connecting [the claimed] omission to its loss," the court held "it is possible for more than one cause to affect the price of a security and, should the case survive to that point, a trier of fact can determine the damages attributable to the fraudulent conduct." *Id.* (citing *Ackerman v. Schwartz*, 947 F.2d 841, 849 (7th Cir. 1991)).

The Second Circuit agrees. "Of course, if the loss was caused by an intervening event, like a general fall in the price of Internet stocks, the chain of causation will not have been established. But such is a matter of proof at trial and not to be decided on a Rule 12(b)(6) motion to dismiss." *Emergent Capital Inv. Mgmt., LLC v. Stonepath Group, Inc.*, 343 F.3d 189, 197 (2d Cir. 2003).

Even at the proof stage, the Fifth Circuit holds plaintiffs need only prove the fraud "caused a significant amount of the decline," explicitly declining "to quantify what fraction of a decline is 'significant.'" *Oscar Private Equity Invs. v. Allegiance Telecom, Inc.*, 487 F.3d 261, 270 (5th Cir. 2007) (Higginbotham, J.).

Because circuits around the country follow the clear guidance from this Court that it is not proper for a district court to apportion causation at the pleading stage, this tacked-on issue is not an appropriate basis for granting certiorari.

CONCLUSION

For the foregoing reasons, the Petition should be denied.

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IN THE

Supreme Court of the United States

GILEAD SCIENCES, INC., JOHN C. MARTIN, JOHN F. MILLIGAN, MARK L. PERRY, NORBERT W. BISCHOFBERGER, ANTHONY CARRACIOLO AND WILLIAM A. LEE,

Petitioners,

v.

TRENT ST. CLARE AND TERRY JOHNSON, ON BEHALF OF THEMSELVES AND ALL OTHERS SIMILARLY SITUATED,

Respondents.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

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RESPONDENTS' SUPPLEMENTAL BRIEF

Underscoring the lack of any split among the circuits on the pleading standard for loss causation, the Fifth Circuit issued a published opinion on April 9, 2009, citing the Ninth Circuit's loss causation decision in this case with approval. *Lormand v. US Unwired, Inc.*, No. 07-30106, __ F.3d __, 2009 U.S. App. LEXIS 7452 (5th Cir. Apr. 9, 2009).

Initially, the Fifth Circuit followed this Court's guidance in *Dura Pharms., Inc. v. Broudo*, 544 U.S.

336 (2005), holding that "for a plaintiff's complaint to adequately *allege* or *plead* [loss causation], it need only set forth 'a short and plain statement of the claim showing that the pleader is entitled to relief,' pursuant to Federal Rules of Civil Procedure 8(a)(2)." *Lormand*, 2009 U.S. App. LEXIS 7452, at *77, emphasis in original. Thus, Petitioners' assertion (Reply 2, 4-5) that the Fifth Circuit applies Rule 9(b) to loss causation allegations is simply wrong. Petitioners' reliance on one word in an earlier unpublished decision by the Fifth Circuit (Pet. 17) never established a split among the circuits. *Lormand* clarifies that no split exists; the Fifth Circuit applies Rule 8 to loss causation pleading.

More specifically, the Fifth Circuit agreed with the Ninth Circuit that, reading *Dura* and *Bell Atl. Corp. v. Twombly*, 550 U.S. 544 (2007), together, "Rule 8(a)(2) requires the plaintiff to allege, in respect to loss causation, a *facially 'plausible' causal relationship* between the fraudulent statements or omissions and plaintiff's economic loss . . . [and] *enough facts* to give rise to a reasonable hope or expectation that discovery will reveal evidence of the foregoing elements of loss causation." *Lormand*, 2009 U.S. App. LEXIS 7452, at *84.[1] The Fifth Circuit's language mirrors the standard articulated by the Ninth Circuit: "sufficient detail to give defendants ample notice of [Investors'] *loss causation theory*, and to give us some assurance that the theory has a *basis in fact*." *In re Gilead Scis. Sec. Litig.*, 536 F.3d 1049, 1056 (9th Cir. 2008). Like the Ninth Circuit–and every other circuit that has reached the issue–the Fifth Circuit requires a plausible theory and some supporting facts.

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[1] Emphasis added unless otherwise noted.

Moreover, like the Ninth Circuit, the Fifth Circuit held that a plaintiff adequately pleads loss causation by *alleging* that the fraud "caused a *significant part* of the depreciation of the stock and plaintiff's economic loss." *Lormand*, 2009 U.S. App. LEXIS 7452, at *84. Indeed, as though it were responding to Petitioners' here, *Lormand* rejected defendants' assertion there that "a more plausible alternate inference may be drawn as to the proximate cause of all of the plaintiff's economic loss." *Id.* at *109. Echoing the Ninth Circuit, the Fifth Circuit explained that "under Rules 8(a)(2) and 12(b)(6), at the pleading stage, the plaintiff is only required to plead a plausible cause of action; [the court] is not authorized or required to determine whether the plaintiff's plausible inference of loss causation is equally or more plausible than other competing inferences. . . ." *Id.* Petitioners' assertion that circuits are split regarding whether apportionment of loss must be *alleged* at the pleading stage–an assertion they attempt to support with a decision at the *proof* stage from the Fifth Circuit (Reply 6 n.4)–does not survive the Fifth Circuit's disposition of this issue.

The Fifth Circuit further agreed with the Ninth Circuit that the "timing issue" of the market's response to certain partial disclosures by defendants "is a factual question, and is not enough to dismiss a complaint that *alleges* a specific causal link. . . ." *Lormand*, 2009 U.S. App. LEXIS 7452, at *111 n.33 (citing *Gilead*, 536 F.3d at 1058), emphasis in original. The court held that loss causation allegations must be considered "in the context of all facts alleged by the complaint." *Id.* at *105. Thus, *Lormand* rejected defendants' fact-bound assertions that the stock price did not respond to a particular disclosure during the class period, concluding that loss causation was

amply pled where "plaintiff alleges that the stock dropped after the last disclosure in the series of disclosure events." *Id.* at *111 n.33.

The Fifth Circuit's holding responds directly to the assertion by Former SEC Commissioners and Officials and Law and Finance Professors that the "timing issue" between the FDA's issuance of a Warning Letter to Gilead, criticizing its off-label marketing practice, and the stock price drop two months later somehow vitiates the concept of market efficiency. SEC Commissioners' *Amicus Curiae* Brief 8. Thus, the Fifth Circuit's analysis in *Lormand* is consistent with the Ninth Circuit's recognition here that the content of the FDA letter *was* incorporated into the stock price, "but it did not contain enough information to significantly undermine Gilead's July 2003 pronouncements concerning demand for Viread." *Gilead*, 536 F.3d at 1058. The market responded "immediately after" the economic *impact* of Gilead's off-label marketing on earnings was revealed. *Id.* As both the Ninth Circuit and the Fifth Circuit recognized, any rule precluding recovery by injured investors in such circumstances would simply reward defendants crafty enough to make partial disclosures–or reveal half truths.

CONCLUSION

The circuits are in harmony. There is no reason for this Court to grant certiorari.

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April 15, 2009

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No. 08-1021

IN THE

Supreme Court of the United States

GILEAD SCIENCES, INC., *et al.*,
Petitioners,

v.

TRENT ST. CLARE, *et al.*,
Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

PETITIONERS' REPLY BRIEF

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PETITIONERS' REPLY BRIEF

Respondents' Brief in Opposition rests on a demonstrably false premise: that *Dura Pharmaceuticals, Inc.* v. *Broudo*, 544 U.S. 336 (2005), "provided a standard for pleading loss causation in securities fraud cases." Opp. 1; see also *id.* at 2 n.1, 14, 16, 17, 24, 26-28, 30. This Court in *Dura* assumed "for argument's sake" that Rule 8's pleading standard applied in that case, and it found the complaint deficient even under the permissive standard of *Conley* v. *Gibson*, 355 U.S. 41 (1957), *abrogated by Bell Atl. Corp.* v. *Twombly*, 550 U.S. 544 (2007). *Dura*, 544 U.S. at 346 (citing *Conley*, 355 U.S. at 47). Respondents mischaracterize an assumption "for argument's sake" as a holding of this Court.

Respondents' false premise is the foundation for their broader assertion that there is no controversy among the lower courts regarding the proper pleading standard. Unsurprisingly, lower courts do not agree. The Fourth Circuit has expressly noted the open question whether Rule 8 or Rule 9(b) applies to loss causation allegations in securities fraud cases.

Teachers' Ret. Sys. v. *Hunter*, 477 F.3d 162, 185-86 (4th Cir. 2007). An earlier (post-*Dura*) Ninth Circuit decision acknowledged that this Court "has not yet answered" whether Rule 8 or Rule 9(b) applies. *Berson* v. *Applied Signal Tech., Inc.*, 527 F.3d 982, 989-90 (9th Cir. 2008). As detailed in the petition, the Fifth and Seventh Circuits have applied Rule 9(b)'s particularity standard to allegations of loss causation after *Dura*. Pet. 17. Certain district courts apply Rule 9(b)'s particularity standard to loss causation, along with other elements of a securities fraud claim.[1] Others have acknowledged the uncertainty regarding the appropriate pleading standard.[2] Ultimately, respondents cannot unite the pleading standards adopted by the lower courts under an ill-defined "some" facts standard, Opp. 23, 24, 27, which respondents claim the Ninth Circuit adopted here. The question is open, the split is real, and only this Court can adopt a uniform, meaningful standard that ensures securities fraud claims are not deployed for their *in terrorem* effect. *Dura*, 544 U.S. at 346.

This case is an ideal vehicle for doing so. Both substantive components of loss causation are at issue: first, that the alleged loss must follow disclosure of

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[1] *See, e.g.*, *Beightol* v. *Navarre Corp.*, No. 4:08cv00010-DPJ-JCS, 2009 WL 169069, at *2 (S.D. Miss. Jan. 26, 2009); *Chien* v. *Skystar Bio Pharm. Co.*, 566 F. Supp. 2d 108, 114 (D. Conn. 2008); *In re First Union Corp. Sec. Litig.*, No. 3:99CV237-H, 2006 WL 163616, at *6 (W.D.N.C. Jan. 20, 2006); *Collier* v. *Aksys Ltd.*, No. 3:04CV1232, 2005 WL 1949868, at *5, 10 (D. Conn. Aug. 15, 2005), *aff'd*, 179 F. App'x 770 (2d Cir. 2006).

[2] *See, e.g.*, *In re Countrywide Fin. Corp. Sec. Litig.*, 588 F. Supp. 2d 1132, 1199 (C.D. Cal. 2008); *In re Dot Hill Sys. Corp. Sec. Litig.*, 594 F. Supp. 2d 1150, 1157 (S.D. Cal. 2008); *In re Rhodia S.A. Sec. Litig.*, 531 F. Supp. 2d 527, 544 (S.D.N.Y. 2007); *Steiner* v. *Medquist Inc.*, No. 04-5487(JBS), 2006 WL 2827740, at *19 n.22 (D.N.J. Sept. 29, 2006).

the alleged fraud, and second, that the losses claimed are attributable to the fraud, not other confounding causes. *Dura*, 544 U.S. at 342-43. Respondents employ a strategy of avoidance with respect to the latter, and of distortion with respect to the former.

Respondents claim plaintiffs need not plead *any* facts that provide a reason to believe they can disentangle non-actionable from actionable causes of a drop in stock price. Opp. 33-34. Respondents are so desperate to avoid this requirement that they treat it as if it were not part of the loss causation requirement itself. *Id.* at 33 (arguing this issue is not fairly included in the question presented, which concerns the pleading standard for "loss causation"). And they pretend as if there were not *three* prior complaints that had attributed the drop in Gilead's stock price to the non-actionable misestimation of inventory stockpiling by wholesalers. *Id.* at 3-4. Respondents have not even tried to argue that the Ninth Circuit's decision concluded that they had alleged even *some* facts "that would allow a factfinder to ascribe some rough proportion of the whole loss to" the alleged off-label marketing scheme, which is precisely what the Second Circuit requires. *Lattanzio* v. *Deloitte & Touche LLP*, 476 F.3d 147, 158 (2d Cir. 2007). The split with the Second Circuit could not be clearer.

Finally, the Opposition highlights the need to clarify the requirement to plead facts—not merely a theory—which show that the alleged loss occurred after the alleged fraud was revealed. Respondents argue that this requirement is satisfied by pleading that the risk concealed by the fraud has materialized and been disclosed, even if the fraud itself has not, Opp. 18, and that there is no requirement that the disclosure be a "mirror image" of the fraud, *id.* at 24

(citing *In re Williams Sec. Litig.*, 2009 WL 388048, at *8 (10th Cir. Feb. 18, 2009)). But even this "materialization of the risk" test has been questioned by courts of appeals. And, on respondents' explication, the Ninth Circuit's decision relaxes that standard to the point where it fails to serve its purpose of separating purely speculative claims from those with concrete prospects for success.

In sum, this Court should grant the petition for the same reason it granted the petition in *Tellabs, Inc.* v. *Makor Issues & Rights, Ltd.*, 127 S. Ct. 2499 (2007): one circuit has articulated a uniquely lax standard of pleading an element of securities fraud even as the other courts of appeals differ over the appropriate more meaningful standard. This Court's review is both necessary and appropriate here.

1. Respondents simply ignore those portions of lower court decisions that cannot be fit into their newly-minted, vague, "some" facts standard. They cannot explain why the Seventh Circuit would have pointed out that a state negligent misrepresentation claim could survive because Rule 8 applied, "not the heightened requirements of Rule 9," even as it dismissed a federal securities fraud claim for failure to plead loss causation adequately. *Tricontinental Indus., Ltd.* v. *Pricewaterhouse Coopers, LLP*, 475 F.3d 824, 839 n.10, 843-44 (7th Cir.), *cert. denied*, 128 S. Ct. 357 (2007). If, as respondents assert, the Seventh Circuit found the allegations of loss causation "implausible," Opp. 22-23 (emphasis omitted), then it would also have dismissed the state negligent misrepresentation claim, which likewise required loss causation. Respondents also casually dismiss, *id.* at 21, the Fifth Circuit's use of the word "particularity" to describe the pleading standard for loss causation, as if that were not the very term used

to distinguish Rule 8 from Rule 9. *Catogas* v. *Cyberonics, Inc.*, 292 F. App'x 311, 312 (5th Cir. 2008) (per curiam). The Seventh and Fifth Circuits apply the "particularity" requirement of Rule 9 to loss causation allegations, contrary to the Ninth Circuit.

Whether Rule 9(b)'s particularity standard or another heightened standard should apply is thus ripe for this Court's consideration. And substantial arguments favor applying Rule 9. Loss causation is readily considered one of the "circumstances constituting fraud," numerous courts prior to the PSLRA had stated that Rule 9 applied to securities fraud claims, and the PSLRA was designed to heighten (not weaken) the pleading requirements for those elements that were not subject to Rule 9(b)'s particularity requirement. See BIO Amicus Br. 9-16.

Even those courts that have not decided whether Rule 9's standard applies have demanded substantially more factual specificity than the Ninth Circuit here. Of particular note, respondents do not even attempt to square the Second Circuit's decision in *Lattanzio* with the Ninth Circuit's conclusion here.

Lattanzio affirmed dismissal of a securities fraud claim because the complaint had not "alleged facts that would allow a factfinder to ascribe some rough proportion of the whole loss to" the alleged fraud. 476 F.3d at 158. This pleading requirement is particularly germane because earlier versions of the complaint (which respondents attempt to brush aside, Opp. 3-4) attributed the loss to a non-fraudulent cause (inaccurate estimation of wholesaler inventory stocking). Respondents do not claim to have alleged any facts that point toward a way to apportion the alleged loss between allegedly fraudulent and non-fraudulent causes.

Respondents claim they need not plead any such facts, arguing that apportionment is not an aspect of loss causation. *Id.* at 33-35. But *Dura* said the ability to exclude other contributing causes is an aspect of loss causation that cannot be ignored. *Dura*, 544 U.S. at 343.[3] Respondents cite cases that are beside the point; they say, uncontroversially, that a plaintiff can recover for securities fraud even if the fraud was not the sole cause of the alleged loss, so long as it is proven to be a substantial cause. See Opp. 34-35. The question here is whether respondents must plead facts showing a reasonably well founded basis for believing that they will be able to prove the alleged fraud was a substantial cause, separate from other causes. That is what *Lattanzio* requires. And *Lattanzio* cannot be made to disappear by citation to pre-*Dura* cases that were less rigorous in policing pleading standards for loss causation. See Opp. 34-35 (citing pre-*Dura* decisions).[4]

2. Respondents' Opposition underlines why this case is an excellent vehicle for providing a uniform pleading standard for loss causation in securities fraud cases. To begin, respondents repeatedly rely on the (erroneous) argument that this Court in *Dura* held that Rule 8 applies to loss causation allegations. They refer only in passing to the Ninth Circuit's unsupported assertion that the Complaint could survive if evaluated under Rule 9(b)'s particularity standard, *id.* at 3, making no effort to explain how

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[3] Respondents' assertion that this issue is not fairly included in the question presented is thus absurd.

[4] The one post-*Dura* case respondents cite held that the inability to separate fraud-caused declines in price from other causes *precluded* class certification. *See Oscar Private Equity Invs.* v. *Allegiance Telecom, Inc.*, 487 F.3d 261, 270-71 (5th Cir. 2007).

their Complaint could meet that more rigorous standard.

More broadly, it is telling how respondents seek to satisfy the most basic aspect of loss causation—the requirement that the loss follow public disclosure of the facts concealed by the alleged fraud, *Dura*, 544 U.S. at 342. Respondents argue that their claim should proceed despite the *disconnect* between the fraud that they allege and what they now admit was disclosed. That disconnect—precisely the point on which the Ninth Circuit departs from the other Circuits—strikes at the heart of the concept of loss causation and demonstrates the urgency of this Court's review.

In their Complaint, respondents assert that demand for Gilead's flagship product was a mirage, with 75%-95% of Viread sales derived from illegal marketing practices. Pet. App. 5a. This fraud, respondents claim, was exposed by some combination of the FDA warning letters, the October 28, 2003 announcement of disappointing third quarter revenues, and a Morgan Stanley analyst report. According to respondents' Complaint, physicians started to reduce the number of prescriptions for Viread in response to the FDA warning letters. ER 85 ¶¶ 200-201. And, again according to the Complaint, the Morgan Stanley report "demonstrat[ed] a sharp drop [in prescriptions] in August 2003, and flattened growth for the rest of the third quarter, as compared to previous quarters." *Id.* ¶ 201. In sum, the fraud allegedly inflated the demand for Viread, and the disclosure supposedly revealed a substantial drop in that demand. The Ninth Circuit deemed this *theory* of loss causation not "per se implausible." Pet. App. 19a.

If the market understood that a fraud, striking at the overwhelming proportion of demand for Gilead's

flagship product, had been revealed at the end of October 2003, causing a drop in stock price, one would expect the respondents to have understood it also and to have pled it. Yet respondents did not allege that theory until their Fourth Amended Complaint more than two years later. The unexplained timing gap suggests that the theory does not reflect what the market understood in October 2003, but has since been manufactured to keep speculative litigation alive.

More importantly, the law require the pleading of specific facts to ensure that a stated *theory* is sufficiently well grounded in reality that it warrants imposing upon the defendant the risks and costs of litigation. *Dura*, 544 U.S. at 347-48. Yet neither respondents now nor the Ninth Circuit below could point to specific facts alleged in the Complaint that backed respondents' theory.

The Morgan Stanley report, which is attached, does not discuss a *drop* in prescriptions in the third quarter of 2003; at most, it shows slower growth in prescriptions. Reply App. 4a-5a. Respondents now admit that is all the report shows, Opp. 27, 31, which is *not* what they alleged in their Complaint. The Ninth Circuit relied on the *theory* without addressing the *facts* that supposedly supported the theory. Pet. App. 8a-9a. Indeed, the report states that "Viread demand continues to grow" but "off a lower base" due to Gilead's misestimation of *second-quarter* wholesaler inventory overstocking. Reply App. 2a.

In addition, the quick recovery of the stock price casts substantial doubt on the notion that the market interpreted events as plaintiffs suggest. If the market believed that the true demand for Viread was weaker than it had been led to believe, it is difficult to imagine why the price would have quickly rebounded.

The one-day decline in Gilead's stock price is consistent with the headline of the Morgan Stanley report and the theory in respondents' prior complaints: a downgrade based on the one-time misestimation of wholesaler inventory stocking. The alleged fraud assumes that Viread's commercial future was in peril. The reaction and commentary of the market suggests nobody thought so.

Respondents assert that the PSLRA's "bounce back" provision warrants ignoring, for pleading purposes, the quick recovery of Gilead's stock price. Opp. 32. The "bounce back" provision is a distraction; it addresses only the calculation of damages for a valid claim. It does not shield theories of loss causation from scrutiny at the pleading stage. The Ninth Circuit ignored the impact of the recovery of Gilead's stock price on the plausibility of respondents' loss causation theory because it considered only the "facial[]" plausibility of the theory. Pet. App. 17a. In evaluating the plausibility of a theory of loss causation, other circuits have considered recovery following an alleged corrective disclosure and the market's failure to react to more direct disclosures than the one at issue. See *Catogas*, 292 F. App'x at 315; *Masters* v. *GlaxoSmithKline*, 271 F. App'x 46, 51 (2d Cir. 2008); *Teachers*, 477 F.3d at 189. Cf. *Oran* v. *Stafford*, 226 F.3d 275, 283 (3d Cir. 2000) (Alito, J.) (looking at four-day price increase following corrective disclosure to show lack of materiality at pleading stage). Once again, the Ninth Circuit's decision diverges from those of other courts.

At bottom, respondents assert that they can ignore the need to plead facts supporting a connection between the supposed fraud and the supposed disclosure that revealed the fraud. Respondents believe they need only plead that the risk concealed

by the fraud has materialized and been disclosed, even if the fraud itself has not. Opp. 18. In their view, the public disclosure need not be a "mirror image" of the fraud. *Id.* at 24 (citing *Williams*, 2009 WL 388048, at *8). But such a "materialization of risk" theory is itself controversial. The Seventh Circuit concluded that "[w]e cannot accept this rendition of *Dura*'s requirements" and required pleading that the concealed facts "'bec[a]me generally known.'" *Tricontinental*, 475 F.3d at 843 (quoting *Dura*, 544 U.S. at 344). The Fifth Circuit requires that "[p]laintiffs must allege . . . that the market reacted negatively to a corrective disclosure, which revealed the falsity of [the defendant's] previous representations regarding" the same subject matter. *Catogas*, 292 F. App'x at 314. Since *Dura*, the Second, Sixth and Eighth Circuits have rejected complaints premised upon "materialization of risk" theories for failure to allege facts showing that the later events were caused by the earlier alleged fraud. See *Lattanzio*, 476 F.3d at 157-58; *Joffee* v. *Lehman Bros.*, 209 F. App'x 80, 81 (2d Cir. 2006); *Schaaf* v. *Residential Funding Corp.*, 517 F.3d 544, 552-53 (8th Cir.), *cert. denied*, 129 S. Ct. 222 (2008); *DE&J Ltd. P'ship* v. *Conaway*, 133 F. App'x 994, 999-1000 (6th Cir. 2005).

Not only is the materialization of risk theory controversial, but respondents here defend an extraordinarily broad version of it. Given the disconnect between the alleged fraud and what was disclosed, respondents are essentially arguing that *any* impact on demand—even an impact that amounts to a merely temporary slowdown in demand growth—is a materialization of the risk concealed by a fraud that supposedly inflated demand. As Judge

McConnell observed in *Williams*, "The zone of risk ... is not infinite in size." 2009 WL 388048, at *11.

The weakening of the pleading requirements for loss causation that respondents defend here will undermine the purposes of requiring loss causation to be pled in the first place. *Dura*, 544 U.S. at 345-48. And, as the amici have well articulated, the harm to companies in growth fields like technology and biotechnology is particularly acute given the volatility they experience in stock prices even under innocent circumstances. BIO Amicus Br. at 6-8; TechNet Amicus Br. 3-8. Biotechnology and other regulated industries subject to frequent regulatory action like the warning letters at issue here will likewise bear the costs of the Ninth Circuit's excessively lax pleading standard. BIO Amicus Br. 5-6; WLF Amicus Br. 16-19. The broad industry support for certiorari forcefully shows the national significance and importance of this issue, especially as we progress through a period of especially high market volatility. NAM Amicus Br. 6-9.

CONCLUSION

For the foregoing reasons, and those stated in the petition, the petition for writ of certiorari should be granted.

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APPENDIX

Morgan Stanley

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North America

United States of America

Biotechnology

Gilead Sciences

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Analysis of Sales/Earnings

October 29, 2003

Viread Surprises — But Not as Usual

STOCK RATING	OVERWEIGHT
Price (October 27, 2003)	$37.42
Price Target	$62
52-Week Range	$70.61 - 31.24

STOCK ratings are relative to the analyst's industry for industry team's coverage universe

GICS SECTOR	HEALTH CARE
US Strategist Weight	14.8%
S&P 500 Weight	13.3%

WHAT'S CHANGED	
Change of Target Price	$60 to $62
Earnings (2003)	to $1.46 from $1.57
Earnings (2004)	to $2.01 from $2.01
Earnings (2005)	to $2.97 from $2.88
Earnings (2006)	to $3.74 from $3.90
Earnings (2007)	to $4.34 from $4.77

- **Gilead Posts a 3Q Disappointment**
  After the close of market on Tuesday, Gilead posted adjusted 3Q EPS of $0.28 per share, well below our aggressive $0.39 and the $0.35 consensus. EPS were impacted by lower Viread sales and significantly greater US Viread inventory reductions. SG&A was lower, partially offsetting.
- **Viread Inventory the Story**
  Higher-than-anticipated Viread inventories entering 3Q, lower end-user demand entering the quarter, and lower wholesaler target inventories combined to have a significant negative impact on reported 3Q Viread sales. 3Q Viread sales totaled $115 million versus our aggressive $172 million estimate and the $155 million consensus.
- **Building from a Lower Base - Remain Overweight**
  We believe Viread demand continues to grow, albeit off a lower base. While the impact is significant to our 4Q revenue forecast, it dissipates over time as the product makes in-roads into underpenetrated markets. Confidence in management's ability to manage inventory and forecast demand will take time to rebuild, in our view.
- **Biotechnology Industry View: In-Line**
  Fundamentals are strong and momentum continues, but we believe the current valuations will make it difficult for the group to outperform the broader markets.

Fiscal Year Ends (Dec. 31)	2002	2003e	2004e	2005e
EPS ($)	0.42	1.46	2.01	2.97
Prior EPS Est. ($)	–	1.57	2.01	2.88
First Call Consensus ($)	0.43	1.42	1.93	2.78
P/E	136.3	29.3	29.6	19.3
P/E Rel. to (local index) (%)	–	–	–	–
Price/Book	–	–	–	–
EV/EBITDA	133.3	29.9	15.4	10.9
Yield (%)	–	–	–	–
Market Cap ($mm)	11,581.9			
Enterprise Value ($mm)	10,869.9			
Debt Cap (08-03) (%)	–			
Return on Equity (08-03) (%)	–			
LT Est EPS Growth (yy - yy) (%)	19.0			
P/E to Growth	–			
Shares Outstanding (mm)	301.4			

Qtrly EPS	2002e as last	2003e curr	2003e prev	2004e curr	2004e prev
Q1	(0.02)	0.21	–	–	–
Q2	0.10	0.46	–	–	–
Q3	0.19	0.28e	0.39e	–	–
Q4	0.17	0.47e	0.48e	–	–

e = Morgan Stanley Research estimates

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Viread Surprises--But Not as Usual

Company Description
Gilead Sciences, headquartered in Foster City, California, is an independent biopharmaceutical company that seeks to provide treatment solutions in the infectious disease and oncology area

Summary and Investment Conclusion
After the close of market on Tuesday, Gilead posted adjusted 3Q EPS (before non-recurring items) of $0.28, well below our aggressive $0.39 estimate, and Street consensus expectations of $0.35. EPS was impacted by lower Viread sales and significantly greater US Viread inventory reductions. SG&A was lower, partially offsetting

Viread sales numbers were the story, as usual, but the numbers reported were quite unusual. It was widely known that Viread sales would be impacted by some drawdown of the significant wholesaler inventory build, which occurred in 2Q. However, a confluence of factors came together to result in a much greater hit in 3Q than anticipated. 1) **Management underestimated the magnitude of the 2Q wholesaler inventory build**, putting it at $25-$30 million, rather than the $33-$37 million it now believes was the case. 2) As a result of the mis-estimation of the contribution of the wholesaler inventory build in 2Q and its contribution to 2Q US sales recorded by Gilead, **calculated 2Q end-user sales figures** were inflated above actual levels, and thus the end-user demand run-rate entering 3Q was actually lower than previously believed. 3) **Wholesalers appear** to have managed down their inventory levels for Viread, at least in the short term, from the one-month level previously, to about half of that now. The result of higher inventories entering the quarter, lower end-user demand entering the quarter, and lower wholesaler target inventories, had a significant effect on the reported 3Q Viread number.

Looking forward however, the story may be getting back to business as usual. The only lingering fundamental factor among the aforementioned is the fact that end-user demand run rates were actually lower than previously believed. Thus, while Viread demand continues to grow, it is off a lower base. The impact of this is meaningful to our 4Q Viread forecast, but dissipates over time as the product should continue to make in-roads into un-penetrated markets. Yet, the Viread issues coming to light in the 3Q announcement should also have a psychological impact, with regard to the degree of confidence in management's ability to manage and forecast Viread demand and inventory levels. We believe this will also impact GILD in the near term, until confidence re-builds with additional prescription and earnings data points.

We adjusted our earnings estimates as outlined below, largely to reflect the lower Viread sales base exiting 3Q. However, we also reduced our R&D and SG&A spending expectations, which in out years, more than offset the modest reductions we took in Viread sales in the out years (as the 3Q hiccup is not expected to have long-term repercussions).

Our new EPS estimates are:

- 2003 goes to $1.46 from $1.57
- 2004 goes to $2.01 from $2.51 (biggest impact from increasing forecast tax rate to 30% from 19%)
- 2005 goes to $2.97 from $2.89
- 2006 goes to $3.74 from $3.60
- 2007 goes to $4.34 from $4.23

Valuation and Risks
Our price target goes to $82 from $86, based on the lower 4Q EPS outlook and lower multiple, partly offset by a higher long-term growth rate off of the lower 2004 EPS base. Our new price target is based on a 1.4 PEG (near the middle of the range for profitable companies) on our new 2004 EPS estimate of $2.01, and long-term (2004-2007) EPS growth rate of 29%.

Despite the setback in confidence and near-term earnings, with the pullback in the shares, we believe that GILD presents an attractive investment opportunity. We believe continued growth in Viread, Hepsera, and Emtriva, regulatory progress with the Viread/Emtriva co-formulation, and improving confidence in the visibility on Viread sales and inventories will drive appreciation from here. The primary risks to the story is the reduced visibility on Viread demand and inventory levels, development timelines for the Viread/Emtriva co-formulation, and increasing competitive environment -- particularly by key competitor, Glaxo.

Quick Look at 3Q Earnings
EPS of $0.28 per share were disappointing due to lower Viread sales, which included a much larger than anticipated impact from inventory draw-downs in the quarter.

- **Total revenues** came in at $200.4 million, versus our estimate of $239.4 million. This is a 50% increase versus 3Q02 but down 16% sequentially. Sales were strong for AmBisome, Hepsera, and Emtriva, but Viread was disappointing.

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- **Viread** reported sales of $115.4 million were well below our aggressive estimate of $172.0 million and the Street consensus of about $154 million ($135-172 million range). Viread sales were up 67% versus 3Q 2002, but down 31% versus 2Q 2003.

  Excluding inventory fluctuations, sales in 3Q were about $150 million (excluding the approximately $33-$37 million inventory reduction in the quarter). This was up about 14% versus 2Q end-user sales of about $132 million (excluding the $25-$30 million inventory build).

  Reported US sales of Viread in 3Q were $59 million, down 49% from the $115 million in reported 2Q sales. However, excluding the inventory impact, US sales of about $94 million in 3Q were up 17% over adjusted 2Q sales of $81 million. The 17% increase in end-user demand included the contribution from a 5.5% price increase instituted in June, and 13.5% increase in IMS reported scrips versus 2Q.

  International Viread sales were $56 million in 3Q, up 9% over 2Q levels. We believe there was minimal impact from FX in Viread sales versus 2Q. However, the typical seasonal slow-down in Europe, as well as unseasonably warm weather, slowed growth below the trend-line.

- **Hepsera** sales of $16.4 million were well above our $14.0 million and compared to the Street consensus of $13.4 million (range $12.4 -18.0 million). This equates to 32% growth versus 2Q 2003 levels.

- **AmBisome** sales were $51.6 million, well above our $44.7 million estimate, and versus Street consensus of $42.9 million (range of $39.6- $50.7 million). The positive surprise was due in part to shortages of a competing product in the European market (which accounts for most of the AmBisome sales), and less than anticipated impact from Pfizer's Vfend and Merck's Cancidas.

  Sales were up 1% sequentially and up 6% year over year. Year-over-year growth benefited from the favorable rise in the Euro versus last year, but sales declined 1% on a unit basis due to ongoing competition from Vfend and Cancidas.

- **Emtriva** sales, in its first quarter on the market, were $6.0 million, versus our $5.0 million forecast, and Street consensus of $4.9 million (range of $2.2-$17 million).

- **Total operating expense** was $108.5 million, well below our $144.0 million forecast on lower sales volumes and lower SG&A expense.

- **R&D** expense came in at $44.9 million (excluding a one-time $13.2 million settlement payment with a vendor, likely related to the earlier mis-randomized adefovir trial). R&D spending was 27% since last year, and up 16% sequentially. This was well below our forecast of $44.0 million. R&D expense increased versus last year due to the January 2003 acquisition of Triangle Pharmaceuticals.

- **SG&A** of $63.6 million came in below our $68.0 million forecast, up 50% from the year earlier, and up 6% sequentially. SG&A versus last year was also boosted by the inclusion of Triangle, beginning in January.

Update on Guidance

Management provided an update on its previously-released guidance (from the 2Q earnings conference call) on today's conference call.

- **Viread:** New guidance of $550-$570 million, lowering the top end of the range from previous guidance of $550-$600 million versus our new $570 million forecast.

- **AmBisome:** Raised to $180-$185 million, up from previous guidance of $170-$180 million versus our new $187 million estimate.

- **Hepsera:** no guidance has been given, but we now forecast $53 million.

- **Emtriva:** no guidance has been given, but we forecast $21 million.

- **Contract Revenue:** $4-$6 million versus our $5 million forecast.

- **Gross Margin:** New guidance of about 86%, at the top end of the prior range of 84% - 86%, and versus our 86.4% estimate.

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- **R&D:** Reduced to $155-$160 million, from $165-$180 million earlier. However, most of the reduction is due to the one-time $13.2 million settlement with a vendor in 3Q (which is not included in our new $172 million forecast). On an apples-to-apples basis, our new R&D estimate is at the high-end of management's new guidance.
- **SG&A:** Management took down the top end of the SG&A guidance range, to $240-$250 million, down from $240-$260 million and versus our new $241 million forecast.
- **Tax Rate:** Mid single digits (due to tax loss carry forwards and no significant accruals for financial accounting purposes yet) versus our 6% forecast.
- **EPS:** There has been no prior EPS guidance, but we forecast $1.46 for 2003, versus the existing Street consensus (prior to the earnings release) of $1.46. Our 4Q EPS forecast is for earnings of $0.47, in line with existing 4Q Street consensus.

Gilead Sciences Revenue and Inventory Details

($ millions)	4Q02*	1Q03	% Chg.	2Q03	% Chg.	3Q03	% Chg.	4Q03E	% Chg.	2003
Reported Revenues	85.0	107.0	26%	167.0	56%	115.4	-31%	180.6	57%	570.0
US Ladamivir Sales	56.3	66.8	19%	80.6	21%	94.4	17%	110.4	17%	352.2
Int'l Ladamivir Sales ***	26.8	39.0	45%	51.4	31%	36.0	-9%	67.2	20%	212.6
Total Ladamivir Sales	83.1	104.8	26%	132.0	26%	130.4	-1%	177.6	18%	564.8
Currency Benefit		3.8		5.0		-		-		8.8
Price Increase	-	-		-		4.9	4%	-		4.9
Underlying Demand Growth - Ladamivir ***			23%		31%		10%		19%	
US Inventory (beg. of period)	13.0	19.3	36%	18.0	-4%	33.0	105%	18.0	-46%	-
Change in US Inventory	1.9	2.2	16%	15.0	581	(15.0)	NM	3.0	NM	5.2
US Inventory (end of period)	19.3	18.0	-8%	33.0	105%	18.0	-46%	21.0	17%	
US Weekly sales rate	4.3	5.1	19%	6.2	21%	7.3	17%	8.5	17%	-
US Weeks of Inventory**	4.5	3.5	-22%	5.3	46%	2.5	-51%	2.5	0%	-
GMS Viread Scripts	130,564	168,350	29%	197,911	17%	313,417	58%			

* 4Q02 Inventory (beginning of period), and Change in Inventory are estimated and shaded
** Calculated on current period run rate (i.e., 4Q03 inventory of 3.0 wks divided by 4Q03 weekly sales of $8.6 mm)
*** Assumes no inventory fluctuations in Europe
**** Revenues, normalized for inventory build-down-down, currency, and price increases (constrained core growth)

e = Morgan Stanley Research estimates

Source: Company data, Morgan Stanley Research

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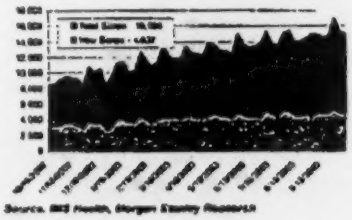
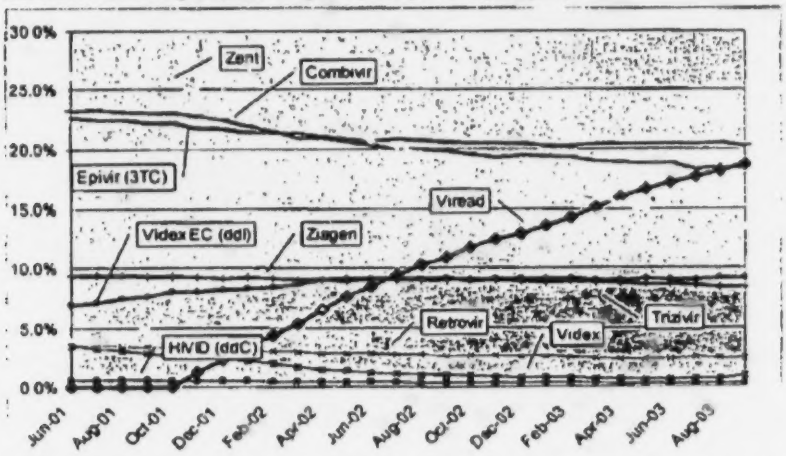
Viread Weekly Scripts (last 52 weeks)



Source: IMS Health, Morgan Stanley Research

Viread Market Share Among Nucleoside Analog Class (monthly IMS data, past 2 years)



Source: IMS Health, Morgan Stanley

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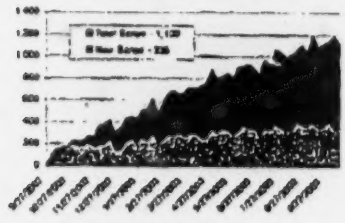
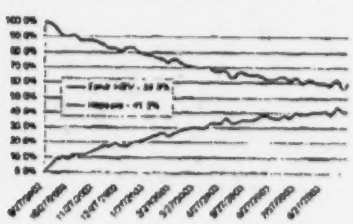
Exhibit 4
Hepsera Weekly Scripe (since Hepsera launch)



Source: IMS Health, Morgan Stanley Research

Exhibit 5
Hepsera Market Share versus Epivir (weekly TRx data)



Source: IMS Health, Morgan Stanley Research

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Gilead Sciences 3Q03 Earnings Snapshot

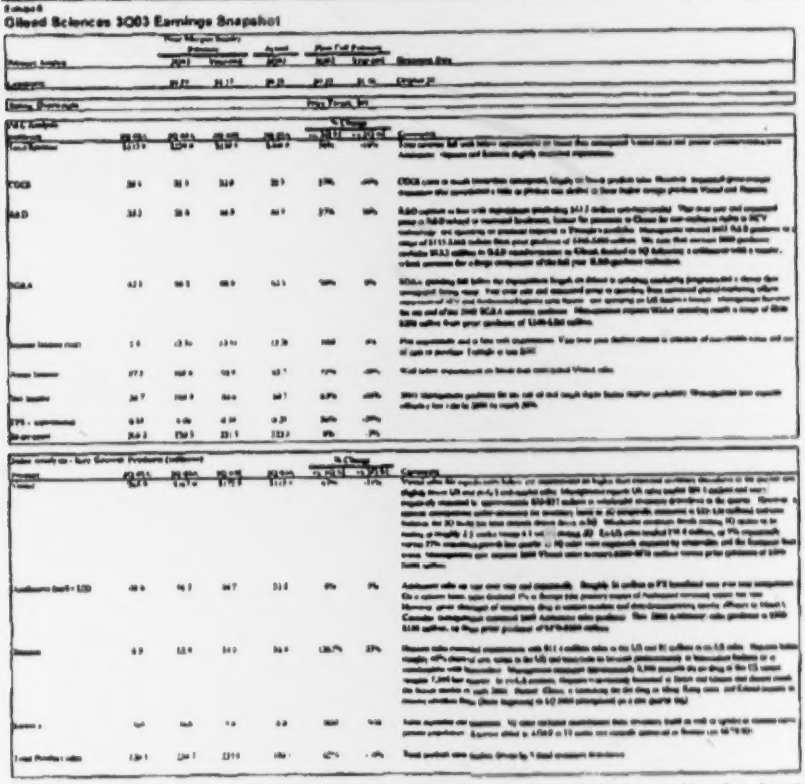
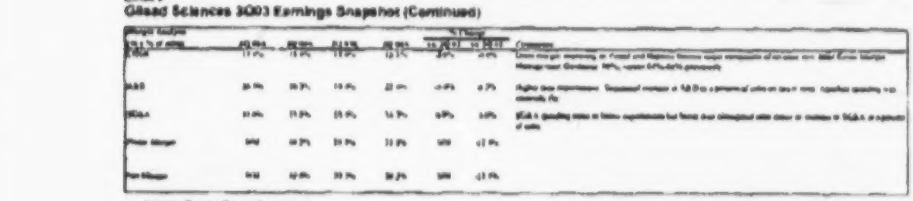


Exhibit 6

Gilead Sciences 3Q03 Earnings Snapshot (Continued)



e = Morgan Stanley Research estimates
Source: Company data, Morgan Stanley Research

Pipeline Update:
Gilead management provided the following update on the pipeline

Hepsera

- During 3Q the company launched Hepsera in Spain, Greece, Austria, Sweden and Norway, and expects an early 2004 launch in Italy. Regulatory approval has been granted in Australia, and the company has filed for approval in Canada, Switzerland and Turkey.

- Partner Glaxo has launched Hepsera in Hong Kong, and is about to launch the product in Singapore. Launches in Taiwan, Korea, China and Japan are expected in 2004/2005.

Viread

- Gilead has initiated the three necessary stability studies required for approval of the co-formulation of Viread and Emtriva. The company has completed the necessary bioequivalence studies designed to demonstrate that the co-formulated pill provides the same blood levels of the drugs as each given separately. The results of this study will be released sometime next year. Management mentioned that they are in discussions with regulatory bodies to confirm the filing strategy for the product, and hope to file in 1H 2004. With a traditional 10-month FDA turnaround time, the company continues to assume approval in early 2005. However, if shorter-duration stability data is sufficient for filing, or the FDA provides a faster review, the co-formulation could be available as early as late 2004.

- About 185 patients have already been enrolled in the 300 patient head-to-head study of Viread, Emtriva plus Efavirenz versus Combivir (AZT and 3TC) plus Efavirenz in treatment naive patients. Patients on the Viread and Emtriva arm will be switched from the individual drugs to the co-formulated product following the review of bioequivalence data by Gilead and the FDA. The patients will be followed for 48 weeks, and the goal is to have data available for presentation around the time of the US product launch of the Viread-Emtriva co-formulation pill.

- At the European AIDS conference currently being held in Warsaw, data from Study 910, an extension of two pivotal clinical studies of Viread in which treatment-experienced HIV patients received Viread for periods of up to four years, was presented. Results showed that Viread was associated with a low incidence and severity of adverse events and laboratory abnormalities.

- Also in Warsaw, data was presented highlighting results from the RECOVER study in which 1,350 highly treatment-experienced patients substituted Viread for a drug from their existing antiretroviral treatment regimen. Results suggested that the use of Viread may improve dyslipidemia associated with stavudine-based regimens, while maintaining viral suppression.

- Yesterday, Abbott presented data using Viread and Emtriva as a "backbone" in their evaluation of Kaletra once a day versus twice a day. Patients in both arms of the study responded well. We believe that this should increase the viability of Emtriva and Viread as it includes these drugs in another once a day HIV treatment protocol. Furthermore,

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Emtriva and Viread should gain increased visibility by way of Abbott's promotional campaign for once-daily Kaletra utilizing this data.

- In late July, Gilead announced a licensing agreement with Japan Tobacco under which Japan Tobacco will commercialize Viread, Emtriva and the future co-formulation of the two products in Japan. Japan Tobacco will submit an application to the relevant Japanese authority and the company expects both Viread and Emtriva to be launched in Japan in 2004.

Emtriva

- Gilead announced that the European Commission granted marketing authorization for Emtriva in all 15 member states of the European Union. Emtriva will be priced at or slightly above Lamivudine's price, similar to the US pricing strategy.

- The company expects data from a Phase III study of FTC (branded as Emtriva for HIV) in chronic HBV shortly, and will update the regulatory strategy following unblinding and review of the data.

GS 7340

- The Viread prodrug, GS 7340, is in an ongoing Phase I/II trial. The goal is to show that GS 7340 retains Viread's beneficial side effects and convenience profile, while providing an even greater potency profile than Viread.

GS 4338

- Lastly, GS 4338, a potent protease inhibitor, with a different resistant profile is being developed for HIV. An IND filing is being worked up, and clinical studies are planned to begin in early 2004.

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Exhibit 7
Anticipated Events for Gilead Sciences

Type	Event	Expected Timing
Product Advancement	Hepsera launch in Singapore	3Q 2003
Regulatory	GS 4104 HD	End 2003
Product Advancement	GS 4104 Phase I start	1H 2004
Product Advancement	DAPD Phase II start in patients with numerous TAMs	2004
	Launch Viread and Emtriva in Japan	2004
Product Advancement	Hepsera launch in Taiwan, Japan, China and Korea	2004-2005
Product Advancement	Launch Viread-Emtriva co-formulation	2005

Source: Company Reports, Morgan Stanley Research

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Exhibit 6

Gilead Sciences Quarterly Income Statement - 2003

(Dollars in millions, except per share data)

	Q1 '03	% Chg	Q2 '03A	% Chg	Q3 '03E	% Chg	Q4 '03E	% Chg	2003E	% Chg
Revenues										
Product Sales										
Ambisome	41.1	3.3%	11.2	-72.8%	44.7	-61.7%	51.6	9.2%	45.3	-12.2%	$153.7	-9.9%
Viread	167.3	294.7%	147.0	-12.1%	172.0	17.0%	113.6	-67.3%	189.6	112.3%	$176.3	15.8%
Hepsera	3.8	58.6	12.4	226.3%	14.9	20.0%	16.4	10.0%	16.9	244.9%	$24.6	45.9%
Gamimune (FPC)	8.6	20.8	6.6	-23.3%	7.9	20.0%	6.6	-16.5%	11.9	-9.8%	$21.9	5.5%
Other	1.9	-61.4%	0.1	-93.4%	0.1	0.0%	0.7	470.0%	0.1	0.0%	$0.5	11.9%
Total Sales	136.9	128.0%	230.7	68.5%	239.8	39.2%	194.1	61.6%	259.3	51.5%	$489.8	17.9%
Royalty	0.9	-148.9%	7.8	5.0%	2.6	-66.7%	4.6	11.9%	12.8	29.9%	$14.7	21.0%
Cosmetic	1.5	-31.7%	2.2	-56.9%	1.8	-20.0%	1.4	-22.9%	2.6	-46.5%	$3.3	-18.2%
Other	0.5	0.0%	0.5	0.0%	0.5	0.0%		0.0%	0.5	0.0%	$0.5	0.0%
Total Revenues	137.8	116.3%	241.2	118.0%	244.5	70.8%	200.4	70.8%	263.9	69.7%	$508.1	84.1%
Cost & Expenses												
Cost of Sales	11.1	77.3%	13.1	81.2%	22.9	74.7%	23.9	27.1%	14.7	77.3%	$34.3	62.7%
SG&A	44.1	22.0%	39.9	-21.7%	44.8	21.7%	48.5	21.1%	47.9	34.9%	$70.9	27.7%
Marketing, G&A	47.9	84.7%	48.2	84.7%	54.9	68.7%	44.6	30.8%	50.9	21.3%	$69.9	39.9%
Other Charges												
Total Operating Expenses	103.1	77.0%	101.3	68.4%	122.6	68.8%	116.9	27.1%	113.7	39.2%	$173.3	46.7%
Operating Income	47.1	9.6%	140.0	198.8%	121.9	73.8%	83.5	24.8%	150.2	238.9%	$334.7	9.8%
Other Income (Expense)												
Net Interest Income	11.01	-184.1%	12.11	234.8%	12.51	3.3%	12.51	234.8%	11.01	-44.7%	$10.19	-26.2%
Income Taxes		0.0%		0.0%		0.0%		0.0%		0.0%	$0.0	0.0%
Gain on Sale Of Subsidiary		0.0%		0.0%		0.0%		0.0%		0.0%	$0.0	0.0%
Pretax Income (Loss)	45.0	9.6%	152.1	237.9%	134.4	73.8%	96.1	24.8%	161.2	196.9%	$344.9	9.8%
Provision for Income Taxes	2.3	9.6%	9.1	9.6%	8.4	9.6%	9.1	9.6%	7.3	9.6%	$16.1	9.6%
Tax Rate	5%		6%		6%		9%		5%		5%	
Net Income From Operations (Loss)	42.7	9.6%	143.0	237.9%	126.0	73.8%	90.3	24.8%	153.9	196.9%	$328.8	9.8%
Non-Recurring Item												
Net Income (Loss)	42.7	9.6%	143.0	237.9%	126.0	73.8%	90.3	24.8%	153.9	196.9%	$328.8	9.8%
EPS From Operations - Basic	$0.03	0.0%	$0.10	233.3%	$0.09	-10.0%	$0.06	-33.3%	$0.09	50.0%	$0.34	13.3%
EPS From Operations - Diluted	$0.03	0.0%	$0.10	233.3%	$0.09	-10.0%	$0.06	-33.3%	$0.09	50.0%	$0.34	13.3%
Basic Shares Outstanding (MM)	1,396.3	2.3%	1,399.5	0.2%	1,399.5	0.0%	1,407.7	0.6%	1,406.6	0.5%	1,403.3	-0.2%
Diluted Shares Outstanding (MM)	1,401.1	0.6%	1,404.3	0.2%	1,404.3	0.0%	1,412.5	0.6%	1,411.4	0.5%	1,408.1	-0.2%

e - Morgan Stanley Research estimates

Source: Company Reports, Morgan Stanley Research

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Exhibit 9
Gilead Sciences Annual Income Statement

(Dollars in millions, except per share data)

	2003	% Chg	2004E	% Chg	2005E	% Chg	2006E	% Chg	2007E	% Chg	2008E	% Chg	2009E	% Chg
Revenue														
Product Sales														
Antiviral	$1,611.7	13%	$1,787.4	9%	$1,874.7	4%	$1,968.7	5%	$2,158.1	9%	$2,409.9	11%	$2,409.9	0%
Viread	330.9	90%	978.1	196%	831.6	-15%	1,062.6	27%	1,241.4	17%	1,241.9	0%	1,241.9	0%
Hepatitis	1.6	88%	8.8	450%	16.8	91%	21.2	26%	26.3	24%	31.1	18%	31.1	0%
Licensing (TTC)	6.0	0%	21.0	250%	71.0	238%	113.0	59%	113.0	0%	113.0	0%	113.0	0%
Other	9.1	-48%	7.1	-22%	7.0	-2%	7.0	0%	7.0	0%	7.0	0%	7.0	0%
Total Product Sales	1,963.4	122%	2,802.6	43%	2,802.3	0%	3,172.5	13%	3,545.8	12%	3,803.0	7%	3,803.0	0%
Royalty	29.3	34%	34.7	18%	26.9	-22%	34.9	30%	39.1	12%	41.0	5%	41.0	0%
Contract	22.3	14%	9.3	-58%	3.0	-68%	3.0	0%	3.0	0%	3.0	0%	3.0	0%
Total Revenue	2,015.0	121%	2,846.6	41%	2,832.2	-1%	3,210.4	13%	3,587.9	12%	3,847.0	7%	3,847.0	0%
Cost & Expenses														
Cost of Sales	449.7	99.3%	514.1	14.3%	594.1	15.6%	674.3	13.5%	761.5	12.9%	815.7	7.1%	815.7	0.0%
R&D	134.0	-37.4%	171.9	28.3%	234.4	36.4%	304.7	30.0%	395.2	29.7%	474.2	20.0%	474.2	20.0%
Marketing, G&A	181.3	44.9%	243.8	34.5%	299.0	22.6%	358.8	20.0%	423.7	18.1%	487.3	15.1%	487.3	15.1%
Other	-	NM	-	NM	-	NM	-	NM	-	NM	-	NM	-	NM
Total Operating Expenses	765.0	0.5%	929.8	21.5%	1,127.5	21.3%	1,337.8	18.6%	1,580.3	18.1%	1,777.2	12.5%	1,777.2	0.0%
Operating Income	1,250.0	191%	1,916.8	53%	1,704.7	-11%	1,872.6	10%	2,007.6	7%	2,069.8	3%	2,069.8	0.0%
Net Interest Income	5.9	-27.3%	(5.4)	NM	19.0	NM	21.8	15.0%	31.9	46.8%	43.8	37.6%	43.8	37.6%
Minority Interest	-	NM	-	NM	-	NM	-	NM	-	NM	-	NM	-	NM
Gain on Sale Of Subsidiary	(24.8)	NM		NM	-	NM	-	NM	-	NM	-	NM		NM
Pretax Income (Loss)	1,231.1	181%	1,911.4	55%	1,723.7	-9.8%	1,894.4	9.9%	2,039.5	7.7%	2,113.6	3.6%	2,113.6	0.0%
Provision For Income Taxes	1.1	NM	0.7	NM	156.6	9900%	208.9	33%	224.4	7%	232.5	3.6%	232.5	0.0%
Tax Rate	NM		0.0%		9.0%		11.0%		11.0%		11.0%		11.0%	
Net Income From Operations (Loss)	1,230.0	181%	1,910.7	55%	1,567.1	-18.0%	1,685.5	7.6%	1,815.1	7.7%	1,881.1	3.6%	1,881.1	0.0%
Equity In Of Unconsolidated Affiliates (Loss)	-	NM	-	NM	-	NM	-	NM	-	NM	-	NM	-	NM
Net Income (Loss)	1,230.0	181%	1,910.7	55%	1,567.1	-18.0%	1,685.5	7.6%	1,815.1	7.7%	1,881.1	3.6%	1,881.1	0.0%
EPS From Operations - Basic	$1.60	91%	$1.82	14%	$1.17	-35.7%	$1.24	6.0%	$1.31	5.6%	$1.33	1.5%	$1.33	0.0%
EPS From Operations - Diluted	$1.42	81%	$1.69	19%	$1.06	-37.3%	$1.12	5.7%	$1.18	5.4%	$1.19	0.8%	$1.19	0.0%
Earnings Per Share, Basic	$1.61	91%	$1.82	13%	$1.17	-35.7%	$1.24	6.0%	$1.31	5.6%	$1.33	1.5%	$1.33	0.0%
Earnings Per Share, Diluted	$1.42	81%	$1.69	19%	$1.06	-37.3%	$1.12	5.7%	$1.18	5.4%	$1.19	0.8%	$1.19	0.0%
Basic Shares Outstanding (mil.)	765.3	2.9%	768.7	0.4%	781.1	1.6%	785.1	0.5%	788.1	0.4%	788.1	0.0%	788.1	0.0%
Diluted Shares Outstanding (mil.)	864.1	6.0%	831.6	-3.8%	821.7	-1.2%	828.6	0.8%	827.6	-0.1%	829.9	0.3%	829.9	0.0%

e - Morgan Stanley Research estimates

Source: Company Reports, Morgan Stanley Research

Please see analyst certification and important disclosures starting on page 13.

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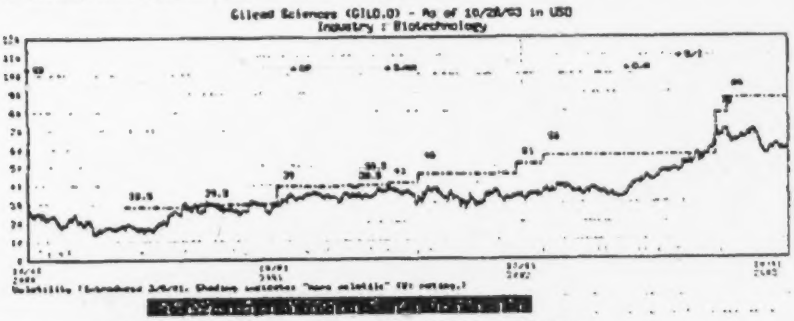

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INDUSTRY COVERAGE: BIOTECHNOLOGY

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Amylin Pharm	AMLN O	E	3/4/03
AtheroGenics	AGIX O	O	3/10/03
Biogen	BGEN O	E	8/24/03
Celgene Corp	CELG O	O	3/18/03
Chiron	CHIR O	V	3/18/03
Cubist Pharmaceuticals	CBST O	U	6/4/03
CV Therapeutics Inc	CVTX O	U	8/7/03
Genentech	DNA N	U	10/10/03
Genzyme General	GENZ O	E	6/20/03
Gilead Sciences	GILD O	O	3/19/03
ICOS Corporation	ICOS O	E	7/16/03
IDEC Pharmaceuticals	IDPH O	E	6/24/03

Company	Ticker	Rating as of	Price at 10/7/03
Inhale Therap	INHL O	E	6/12/03
MedImmune	MEDI O	E	3/17/03
Millennium Pharma	MLNM O	E	6/23/03
Neurocrine Biosciences Inc	NBIX O	E	7/7/03
NPS Pharmaceuticals	NPSP O	O	6/3/03
OSI Pharmaceuticals	OSIP O	O	6/13/03
Regeneron	REGN O	E	6/10/03
The Medicines Company	MDCO O	O	6/12/02
Trimeris	TRMS O	E	6/12/02
Vertex Pharmaceuticals	VRTX O	U	6/15/00

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No. 08-1021

IN THE
Supreme Court of the United States

GILEAD SCIENCES, INC., ET AL.,
Petitioners,

v.

TRENT ST. CLARE, ET AL.,
Respondents.

ON PETITION FOR A WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

BRIEF FOR THE BIOTECHNOLOGY INDUSTRY ORGANIZATION, THE BAY AREA BIOSCIENCE ASSOCIATION, AND BIOCOM AS *AMICI CURIAE* SUPPORTING PETITIONERS

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INTEREST OF *AMICI CURIAE*

This brief *amici curiae* in support of Petitioners is filed on behalf of the Biotechnology Industry Organization (BIO), the Bay Area Bioscience Association (BayBio), and BIOCOM.[1]

As the principal trade association of the biotechnology industry, BIO represents more than 1200 members, many of which are publicly traded companies. Petitioner Gilead Sciences, Inc. is a BIO member. BIO regularly files *amicus curiae* briefs in cases that present issues of vital concern to the industry. *See, e.g.*, *Wyeth v. Levine*, 555 U.S. ___ (2009); *Quanta Computer, Inc. v. LG Elecs., Inc.*, 128 S. Ct. 2109 (2008); *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398 (2007); *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388 (2006).

BayBio is a trade association representing over 450 life sciences companies and affiliated organizations in Northern California, including Gilead. BayBio members are focused on research and product development and rely on access to public markets to fund their activities.

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[1] Pursuant to Rule 37.6, *amici* affirm that no counsel for a party authored this brief in whole or in part, and no party or counsel for a party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than *amici*, their members, or their counsel made a monetary contribution to its preparation or submission. Pursuant to Rule 37.2, counsel of record for all parties received timely notice of *amici*'s intention to file this brief. The parties have consented in writing to the filing of this brief.

BIOCOM is a trade association representing over 575 life sciences companies, service providers, and research institutions in Southern California.

Amici have a significant interest in the issue in this case. Publicly traded biotechnology companies, which are subject to close regulatory scrutiny by the Food and Drug Administration (FDA), experience high stock price volatility due to the nature of their research-driven industry. This combination of regulation and volatility makes every biotechnology company a target for private securities fraud lawsuits. The potential for harm is illustrated by the facts of this case, in which loss causation is alleged to depend on regulatory interactions between a biotechnology company and the FDA. The court of appeals' decision, which applied an overly lenient pleading standard to the allegations of loss causation, encourages strike suits against the biotechnology industry. *Amici*'s members should spend their resources expanding the boundaries of science, not defending baseless securities fraud lawsuits. *Amici* respectfully request that this Court grant the petition and clarify the pleading standard for loss causation in securities fraud cases.

STATEMENT

1. Respondents brought this suit against Petitioners in the United States District Court for the Northern District of California, alleging securities fraud in violation of Section 10(b) of the Securities Exchange Act of 1934, 15 U.S.C. § 78j(b), and SEC Rule 10b-5, 15 C.F.R. § 240.10b-5. Respondents sought in their Fourth Amended Complaint to attribute an October 2003 drop in Gilead's stock price to the disclosure, nearly three

months earlier, of an FDA Warning Letter to the company concerning its drug Viread, an antiretroviral agent used to treat HIV/AIDS. In prior complaints, Respondents unsuccessfully asserted that Petitioners fraudulently misrepresented the extent to which wholesalers had increased their inventories of Viread. *See* Pet. App. 77a–78a (rejecting these allegations). After additional setbacks in the district court, Respondents alleged in their Fourth Amended Complaint that Petitioners fraudulently failed to disclose the extent to which sales of Viread were the result of off-label marketing in violation of FDA regulations. *Id.* at 22a–27a.

Under the Private Securities Litigation Reform Act of 1995 (PSLRA), Pub. L. No. 104-67, 109 Stat. 737, Respondents bore "the burden of proving that the act or omission of the defendant alleged to violate this chapter caused the loss for which the plaintiff seeks to recover damages." 15 U.S.C. § 78u-4(b)(4). According to Respondents' current theory of loss causation, public disclosure of the FDA Warning Letter led to a decrease in demand for Viread among prescribing physicians, which led to a decrease in sales of the drug, which in turn led to a decrease in the price of Gilead's stock as investors reacted to this information. Pet. App. 34a, 38a n.12.

The district court rejected this theory and dismissed the Fourth Amended Complaint pursuant to Federal Rule of Civil Procedure 12(b)(6). Pet. App. 39a. Despite its view that the heightened pleading standard of Rule 9(b) did not apply to loss causation, Pet. App. 36a, the district court nevertheless held that Respondents had failed to plead this necessary

element. The district court identified two flaws under *Dura Pharmaceuticals, Inc. v. Broudo*, 544 U.S. 336 (2005). Respondents failed to allege that the market understood the FDA's objection to off-label marketing of Viread to have resulted in decreased demand for the drug. Pet. App. 34a–36a & n.9, 39a n.14; *see also* Pet. 20–24. Respondents also failed to show that they could isolate loss attributable to the alleged fraud from other causes of the drop in Gilead's stock price. Pet. App. 38a–39a; *see also* Pet. 24–27.

2. The United States Court of Appeals for the Ninth Circuit reversed. Pet. App. 20a. The court of appeals noted that *Dura* left open the question of the pleading standard for loss causation—specifically, of whether to apply Rule 8(a)(2) or Rule 9(b). Pet. App. 14a. While purporting to avoid resolving that question, the court of appeals went on to adopt a lenient standard for pleading loss causation in securities fraud cases. Borrowing language from this Court's decision in *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007), which construed Rule 8(a)(2), the court of appeals held that a complaint may not be dismissed for failing to allege loss causation "so long as the plaintiff alleges facts to support a theory that is not facially implausible." Pet. App. 17a. The court of appeals concluded that Respondents' loss causation allegations met that standard, *id.* at 20a, even though they were at odds with Respondents' prior theories of loss causation.

REASONS FOR GRANTING THE PETITION

I. The Biotechnology Industry Will Be Particularly Vulnerable To Baseless Lawsuits Under The Court Of Appeals' Inappropriately Lenient Pleading Standard For Loss Causation.

Owing to the nature of the industry in which they operate, publicly traded biotechnology companies are particularly susceptible to strike suits under the court of appeals' lenient pleading standard for loss causation. The court of appeals allowed this Section 10(b) action to proceed on the basis of a thin factual predicate. Respondents' allegation of loss causation comes down to two facts: an FDA Warning Letter and a drop in Gilead's stock price. Neither event is uncommon in the heavily regulated and highly volatile biotechnology industry. But under the court of appeals' pleading standard, a biotechnology company will be exposed to a private securities fraud lawsuit whenever a dip in stock price has been preceded by a regulatory notice during the previous quarter. By restoring a suitably rigorous pleading standard for loss causation, this Court can allow biotechnology companies to focus on innovation rather than litigation.

The importance of biotechnology to modern society is reflected in the regulatory scrutiny to which the industry is subject. Biotechnology innovations provide life-saving medical treatments and diagnostic procedures, disease- or herbicide-resistant crops, and a host of promising solutions for the world's environmental, medical, and agricultural

challenges, including the development of non-fossil, renewable sources of energy. From the food we eat to the human genome, the work of the biotechnology industry affects crucial areas of our shared experience. Federal agencies like the FDA therefore pay close attention to the field. As part of its regulatory program, the FDA will issue a Warning Letter if it finds that a regulatory violation has occurred. *See* 21 U.S.C. § 336 (authorizing "suitable written notice or warning" in response to "minor violations"). These Warning Letters are fairly common. *See* Peter Barton Hutt, *The State of Science at the Food and Drug Administration*, 60 ADMIN. L. REV. 431, 466 (2008) (noting that the FDA issued 2265 Warning Letters from 2004 to 2007). Indeed, the issuance of a Warning Letter to Gilead was so unremarkable that the market attributed no negative weight to the event when it was disclosed. *See* Pet. App. 35a.

Publicly traded biotechnology companies are also subject to high stock price volatility. Biotechnology innovations are the product of massive investments in research and development.[2] The time required to move a drug from clinical development

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[2] FED. TRADE COMM'N, TO PROMOTE INNOVATION ch. 3, at 16 (2003) ("R&D is particularly lengthy for biotechnology firms, because biotechnology innovation is more uncertain than innovation in other industries."); *Moving Research from the Bench to the Bedside: Hearing Before the Subcomm. on Health of the H. Comm. on Energy & Commerce*, 108th Cong. 47 (2003) (testimony of Phyllis Gardner, M.D., Senior Associate Dean, Stanford University) ("The biotechnology industry is the most research and development [intensive] industry in the world.").

through regulatory approval and into the market averages almost ninety-eight months. Joseph A. DiMasi & Henry G. Grabowski, *The Cost of Biopharmaceutical R&D: Is Biotech Different?*, 28 MANAGERIAL & DECISION ECON. 469, 473 (2007). The development and regulatory approval processes for biotechnology crops and other products are similarly extensive and fraught with risk. Moreover, the closely regulated nature of the biotechnology industry makes it especially sensitive to changes in government policy. Taken together, these factors create the potential for large swings in the price of a given biotechnology company's stock.

Respondents capitalized on the regulation and volatility inherent in the biotechnology industry. In connection with its marketing of Viread, Gilead received (and promptly disclosed) one of the many Warning Letters the FDA issues each year. Approximately three months later, Gilead's stock price dropped after the company filed a Form 10-Q showing that Viread revenue had declined, most likely as a result of wholesaler inventory adjustments (as analysts reported and Respondents originally alleged). These two events, which could have happened to any biotechnology company, prompted a private Section 10(b) action.

The loss causation requirement should have halted this opportunistic lawsuit at the pleading stage. Respondents failed to plead with particularity facts to support their theory that the Warning Letter depressed demand for Viread among prescribing physicians. Respondents also failed to plead with particularity facts to support the notion that the market was aware that Gilead's supposed off-label

promotion threatened Viread revenues. The court of appeals, however, allowed the suit to go forward on the ground that Respondents' loss causation theory is "not facially implausible," Pet. App. 17a, forcing Petitioners to defend this baseless Section 10(b) action at great cost to Gilead and its shareholders.

Gilead's experience is a harbinger of problems to come for the biotechnology industry. Other biotechnology companies will undoubtedly suffer an FDA Warning Letter followed by an unrelated drop in stock price several months later. Under the pleading standard for loss causation announced in this case, these companies will now suffer Section 10(b) lawsuits, too. In the Second, Fourth, Fifth, Seventh, and Eighth Circuits, investigation must precede litigation: securities fraud plaintiffs will be obliged to allege particularized facts that establish the connection between the regulatory action and the dip in stock price. *See* Pet. 17–19. But in the Ninth Circuit, the occurrence of two relatively common events—even if they are months apart—permits an immediate strike suit.

II. The Court of Appeals Adopted The Wrong Pleading Standard For Loss Causation.

This case presents a critically important question concerning pleading requirements under the PSLRA for private securities fraud actions. In *Dura Pharmaceuticals, Inc. v. Broudo*, 544 U.S. 336 (2005), this Court declined the Solicitor General's invitation to address the pleading standard for loss causation in a Section 10(b) action. In the absence of direction from this Court, the lower courts have been confused and divided over the proper pleading standard for loss causation. While some courts have

correctly applied Rule 9(b), and others have applied a standard resembling Rule 9(b), *see* Pet. 17–19, the Ninth Circuit has adopted a watered-down standard that cannot be squared with Congress's intent in enacting the PSLRA, or with Rule 9(b)'s requirement that "the circumstances constituting fraud" must be pleaded "with particularity." This Court should grant review and clarify that Rule 9(b) applies to loss causation allegations under the PSLRA.

A. Enactment Of The PSLRA Created A Question Regarding The Relationship Between That Statute And Rule 9(b).

The federal courts have inferred from Section 10(b) and SEC Rule 10b-5 a private cause of action that Congress did not provide. *Superintendent of Ins. v. Bankers Life & Cas. Co.*, 404 U.S. 6, 13 n.9 (1971); *see Blue Chip Stamps v. Manor Drug Stores*, 421 U.S. 723, 737 (1975) (describing this "judicial oak which has grown from little more than a legislative acorn"). As this Court recently explained, the elements of this Section 10(b) action include:

> (1) *a material misrepresentation (or omission)*;
>
> (2) *scienter*, *i.e.*, a wrongful state of mind;
>
> (3) *a connection with the purchase or sale of a security*;
>
> (4) *reliance*, often referred to in cases involving public securities markets (fraud-on-the-market cases) as "transaction causation";
>
> (5) *economic loss*, 15 U. S. C. § 78u-4(b)(4); and
>
> (6) *"loss causation," i.e.*, a causal connection between the material misrepresentation and the loss, *ibid.*

Dura, 544 U.S. at 341–42 (citations omitted).[3]

Prior to 1995, the courts of appeals were unanimous in subjecting these Section 10(b) actions to the heightened pleading standard of Rule 9(b).[4] *See Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 127 S. Ct. 2499, 2507 (2007) ("Prior to the enactment of the PSLRA, the sufficiency of a complaint for

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[3] Although the *Dura* Court cited only the PSLRA in identifying the loss causation element, that element was originally a judicial creation. *See Bastian v. Petren Res. Corp.*, 892 F.2d 680, 683–86 (7th Cir. 1990) (Posner, J.); *Chem. Bank v. Arthur Andersen & Co.*, 726 F.2d 930, 943 n.23 (2d Cir. 1984) (Friendly, J.); *Huddleston v. Herman & MacLean*, 640 F.2d 534, 549 (5th Cir. 1981), *rev'd on other grounds*, 459 U.S. 375 (1983); *Schlick v. Penn-Dixie Cement Corp.*, 507 F.2d 374, 380 (2d Cir. 1974).

[4] *E.g.*, *Kowal v. MCI Commc'ns Corp.*, 16 F.3d 1271, 1277–79 (D.C. Cir. 1994); *Romani v. Shearson Lehman Hutton*, 929 F.2d 875, 878–80 (1st Cir. 1991); *Denny v. Barber*, 576 F.2d 465, 468–70 (2d Cir. 1978) (Friendly, J.); *In re Donald J. Trump Casino Sec. Litig.*, 7 F.3d 357, 373 n.17 (3d Cir. 1993) (Becker, J.); *Hillson Partners Ltd. P'ship v. Adage, Inc.*, 42 F.3d 204, 209 (4th Cir. 1994); *Shushany v. Allwaste, Inc.*, 992 F.2d 517, 520–21 (5th Cir. 1993); *Kellman v. ICS, Inc.*, 447 F.2d 1305, 1309 (6th Cir. 1971); *Schaefer v. First Nat'l Bank of Lincolnwood*, 509 F.2d 1287, 1297 (7th Cir. 1975); *Knox v. Lichtenstein*, 654 F.2d 19, 20, 22 (8th Cir. 1981); *In re GlenFed, Inc. Sec. Litig.*, 42 F.3d 1541, 1545 & n.3 (9th Cir. 1994) (en banc); *Seattle-First Nat'l Bank v. Carlstedt*, 800 F.2d 1008, 1010 (10th Cir. 1986) (per curiam); *Friedlander v. Nims*, 755 F.2d 810, 812–14 (11th Cir. 1985). Several courts specifically applied Rule 9(b) to the judicially created loss causation element for Section 10(b) actions. *See, e.g.*, *Aquino v. Trupin*, 833 F. Supp. 336, 342 (S.D.N.Y. 1993); *In re Sahlen & Assocs., Inc. Sec. Litig.*, 773 F. Supp. 342, 351 (S.D. Fla. 1991); *Ames v. Uranus, Inc.*, No. 92-2170, 1993 WL 106896, at *6 (D. Kan. 1993).

securities fraud was governed not by Rule 8, but by the heightened pleading standard set forth in Rule 9(b)."). Rule 9(b) obliges a party to "state with particularity the circumstances constituting fraud," although scienter "may be alleged generally."

With the enactment of the PSLRA in 1995, Congress "imposed statutory requirements" on the judicially created Section 10(b) action. *Dura*, 544 U.S. at 341. These requirements were calculated "to deter or at least quickly dispose of those suits whose nuisance value outweighs their merits." *Merrill Lynch, Pierce, Fenner & Smith Inc. v. Dabit*, 547 U.S. 71, 81–82 (2006); *see Tellabs, Inc.*, 127 S. Ct. at 2508 (The PSLRA was "[d]esigned to curb perceived abuses of the § 10(b) private action."). Among other things, Congress codified at 15 U.S.C. § 78u-4(b)(4) the loss causation requirement previously recognized by the courts. *See* JAMES D. COX ET AL., SECURITIES REGULATION: CASES AND MATERIALS 702 (5th ed. 2006).

As part of its effort to curb strike suits, Congress also altered the pleading standard for private securities fraud actions. *See* 5A CHARLES ALAN WRIGHT & ARTHUR R. MILLER, FEDERAL PRACTICE & PROCEDURE § 1301.1, at 298 (3d ed. 2004) ("Concerned that Federal Rule 9(b) was not being applied effectively by the federal courts to prevent [frivolous securities class action lawsuits], Congress amended the Securities Exchange Act of 1934 . . . to include unique pleading requirements for private actions alleging securities fraud."). This marked a departure from Congress's traditional silence on the subject of pleading standards under the Federal Rules of Civil Procedure. *See* 4 CHARLES

ALAN WRIGHT & ARTHUR R. MILLER, FEDERAL PRACTICE & PROCEDURE § 1001, at 7–10 (3d ed. 2002) (recounting limited congressional modifications to the Federal Rules of Civil Procedure).

The PSLRA imposed stringent new pleading requirements for two elements of the Section 10(b) action. First, it required that "the complaint shall specify each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and, if an allegation regarding the statement or omission is made on information and belief, the complaint shall state with particularity all facts on which that belief is formed." 15 U.S.C. § 78u-4(b)(1). Second, on the issue of scienter, which Rule 9(b) otherwise permits to be "alleged generally," the PSLRA required that "the complaint shall, with respect to each act or omission alleged to violate this chapter, state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." *Id.* § 78u-4(b)(2).

These PSLRA pleading requirements, which only govern misrepresentation and scienter, do not cover every element of the Section 10(b) action. *See Dura*, 544 U.S. at 341–42 (listing six elements). Of particular importance in this case, the PSLRA does not specify a pleading standard for loss causation. *See* 15 U.S.C. § 78u-4(b)(4). The incomplete coverage of the PSLRA's pleading requirements raises the question of what standard governs the statutory element of loss causation where the statute is silent. As we explain below, the answer is clear that Rule 9(b) rather than Rule 8(a)(2) applies.

B. The PSLRA Does Not Displace The Rule 9(b) Pleading Standard For Loss Causation In Section 10(b) Actions.

Rule 9(b) and the PSLRA operate together to provide the pleading standard for securities fraud actions. Where the PSLRA specifies the pleading standard for a particular element of the Section 10(b) action, such as for scienter, the statute trumps the Rule. The other elements of the securities fraud action, including loss causation, should remain subject to Rule 9(b). As the Solicitor General argued in *Dura*:

> Because loss causation is an element of the plaintiff's affirmative case, a complaint must contain allegations that establish the element either directly or inferentially. And because loss causation is an element of a fraud cause of action, the allegations must be "stated with particularity," Fed. R. Civ. P. 9(b), and must satisfy the pleading requirements added to the 1934 Act by the PSLRA, see 15 U.S.C. 78u-4(b)(1) and (2).

Brief for the United States as Amicus Curiae Supporting Petitioners, *Dura Pharms., Inc. v. Broudo*, 544 U.S. 336 (2005) (No. 03-932), 2004 WL 2069564, at *14–*15 (citation omitted). This Court declined the Solicitor General's invitation to address the issue in *Dura*, 544 U.S. at 346, but should now take this case to clarify that Rule 9(b) provides the pleading standard where the PSLRA is silent.

Rule 9(b), which the courts of appeals uniformly applied to Section 10(b) actions before the PSLRA, provides that a party alleging fraud "must

state with particularity the circumstances constituting fraud." The judicially created loss causation element of the Section 10(b) action, as codified in the PSLRA, is among the "circumstances" of the fraud that must be pleaded with particularity. *See Teachers' Ret. Sys. v. Hunter*, 477 F.3d 162, 186 (4th Cir. 2007) ("A strong case can be made that because loss causation is among the circumstances constituting fraud for which Rule 9(b) demands particularity, loss causation should be pleaded with particularity.") (internal quotation marks omitted); *In re Initial Pub. Offering Sec. Litig.*, 241 F. Supp. 2d 281, 336 (S.D.N.Y. 2003) (holding that "Rule 9(b) governs the pleading of the remaining elements of the claims: loss causation, transaction causation, reliance and damages"). Were it otherwise, Rule 9(b) would list loss causation alongside scienter as an element that "may be alleged generally." *Cf. Leatherman v. Tarrant County Narcotics Intelligence & Coordination Unit*, 507 U.S. 163, 168 (1993) ("*Expressio unius est exclusio alterius.*").

Nothing in the PSLRA suggests that Congress intended to alter Rule 9(b)'s pleading requirement for loss causation. The PSLRA did strengthen the pleading standard for the misrepresentation and scienter elements of the Section 10(b) action. *See* 15 U.S.C. § 78u-4(b)(1)–(2). As to these elements, courts have correctly accorded controlling effect to Congress's intent to modify the pleading standards. *See, e.g., In re Advanta Corp. Sec. Litig.*, 180 F.3d 525, 531 n.5 (3d Cir. 1999) ("Rule 9(b)'s provision allowing state of mind to be averred generally conflicts with the Reform Act's requirement that plaintiffs 'state with particularity facts giving rise to

a strong inference' of scienter. In that sense, we believe the Reform Act supersedes Rule 9(b) as it relates to Rule 10b-5 actions.") (citation omitted). But the PSLRA did not provide a pleading standard for loss causation, *see* 15 U.S.C. § 78u-4(b)(4), leaving nothing with which Rule 9(b) could conflict. *See In re Initial Pub. Offering*, 241 F. Supp. 2d at 335 ("Congress intended that the PSLRA supercede the Federal Rules only as to those elements which the PSLRA explicitly mentions (*i.e.*, scienter and material misstatements and omissions). In all other respects, the Rules govern these pleadings.").

Congress's silence on the subject of pleading loss causation does not suggest that the PSLRA was calculated to disturb the preexisting Rule 9(b) standard for securities fraud actions. In light of the PSLRA's purpose of preventing securities fraud strike suits, there is no reason to believe that Congress meant to relax the plaintiff's burden at the pleading stage.

The legislative history is informative. The Senate Committee Report discusses loss causation under the heading, "*A strong pleading requirement.*" S. REP. NO. 104-98, at 15 (1995) ("The Committee also requires the plaintiff to show that the misstatement or loss [sic] alleged in the complaint caused the loss incurred by the plaintiff."). One would not expect to see loss causation discussed as part of the PSLRA's "*strong pleading requirement*" if Congress had intended to weaken the pleading standard for loss causation by displacing Rule 9(b), presumably with the more lenient standard of Rule 8(a)(2). In the absence of congressional intent to displace it, Rule 9(b) should be held to provide the

pleading standard for Section 10(b) actions as to elements, like loss causation, on which the statute is silent.

C. The Court Of Appeals Erred By Adopting And Applying A Rule 8(a)(2) Standard To Loss Causation.

Rather than apply Rule 9(b)'s particularity requirement to the loss causation allegations in the Fourth Amended Complaint, the court of appeals applied the more lenient standard of Rule 8(a)(2), which was recently interpreted in *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 127 S. Ct. 1955 (2007). Notwithstanding its statement that "[w]e need not resolve this issue today," Pet. App. 14a, the court of appeals effectively held Rule 9(b) inapplicable to allegations of loss causation in a Section 10(b) action by adopting a Rule 8(a)(2) standard. The court of appeals erred in so holding.

In reviewing Respondents' allegations of loss causation, the court of appeals was guided by its permissive reading of *Twombly*. The court began by quoting *Twombly* for the proposition that "[t]he complaint is properly dismissed if it fails to 'plead "enough facts to state a claim to relief that is plausible on its face." ' " Pet. App. 12a (quoting *Weber v. Dep't of Veterans Affairs*, 521 F.3d 1061, 1065 (9th Cir. 2008) (quoting *Twombly*, 127 S. Ct. at 1974)). The court continued:

> But so long as the plaintiff alleges facts to support a [loss causation] theory that is not facially implausible, the court's skepticism is best reserved for later stages of the proceedings when the plaintiff's case can be

> rejected on evidentiary grounds. "[A] well-pleaded complaint may proceed even if it strikes a savvy judge that actual proof of those facts is improbable, and that a recovery is very remote and unlikely."

Id. at 17a (quoting *Twombly*, 127 S. Ct. at 1965 (second brackets in court of appeals decision)). The court distilled from *Twombly* a lenient rule to govern loss causation: "So long as the complaint alleges facts that, if taken as true, plausibly establish loss causation, a Rule 12(b)(6) dismissal is inappropriate. This is not 'a probability requirement . . . it simply calls for enough fact to raise a reasonable expectation that discovery will reveal evidence of loss causation." *Id.* at 18a (quoting *Twombly*, 127 S. Ct. at 1965 (ellipses in court of appeals decision)). The court concluded that Respondents satisfied its *Twombly* rule for pleading loss causation. *Id.* at 20a (quoting *Twombly*, 127 S. Ct. at 1965).

The court of appeals did not faithfully apply Rule 8(a)(2) as construed in *Twombly*. Respondents' current theory of loss causation is not plausible in light of (1) the scant facts they have alleged to support it and (2) the existence of facts contradicting their theory. *See* Pet. App. 33a-39a & nn.9, 10, 12, 14 (finding allegations too speculative to satisfy Rule 8(a)(2) standard). Nonetheless, the court of appeals' heavy reliance on *Twombly* undermines its conclusion that Respondents could have satisfied Rule 9(b). *Twombly*, after all, was a Rule 8(a)(2) case. *See* 127 S. Ct. at 1964–69; *id.* at 1975–77 (Stevens, J., dissenting). Whether the Fourth Amended Complaint could withstand *Twombly*'s pleading standard does not answer whether it

satisfies the more stringent standard of Rule 9(b). *See id.* at 1973 n.14 (majority opinion) (distinguishing the heightened Rule 9(b) standard, which the Court did "not apply," from the applicable, less demanding standard of Rule 8(a)(2)).

In adopting a "not facially implausible theory" standard based on Rule 8(a)(2), the Ninth Circuit has created a split of authority with the Seventh and Fifth Circuits, which have correctly applied the Rule 9(b) standard to loss causation. *See Tricontinental Indus., Ltd. v. PricewaterhouseCoopers, LLP*, 475 F.3d 824, 833, 843–44 (7th Cir. 2007); *Catogas v. Cyberonics, Inc.*, 292 Fed. App'x 311, 312 (5th Cir. 2008) (per curiam); *see also* JAMES D. COX ET AL., SECURITIES REGULATION: CASES AND MATERIALS 718 (5th ed. 2006) (attributing to the Second Circuit the view that "loss causation . . . must be pleaded with particularity under Rule 9(b)," citing *Lentell v. Merrill Lynch & Co.*, 396 F.3d 161 (2d Cir. 2005)). This division of authority frustrates Congress's goal of bringing uniformity to securities fraud pleading standards by enacting the PSLRA. *See Tellabs, Inc.*, 127 S. Ct. at 2508 ("Setting a uniform pleading standard for § 10(b) actions was among Congress' objectives when it enacted the PSLRA."). This Court should take the opportunity to restore uniformity by clarifying that Rule 9(b) applies to allegations of loss causation in securities fraud cases.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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Supreme Court of the United States

GILEAD SCIENCES, INC., *et al.*,
Petitioners,

v.

TRENT ST. CLARE, *et al.*,
Respondents.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

BRIEF OF THE CIVIL JUSTICE ASSOCIATION OF CALIFORNIA AS *AMICUS CURIAE* IN SUPPORT OF PETITIONERS

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INTEREST OF *AMICUS CURIAE*[1]

The Civil Justice Association of California ("CJAC" or "amicus")[2] is vitally interested in securing the Court's review of the important issue this case presents – *viz.*, whether a federal securities fraud complaint under Section 10(b) of the Securities Exchange Act must plead facts sufficiently specific to support a reasonable, non-speculative belief that the plaintiff can ultimately prove "loss causation".

CJAC is a more than thirty year old non-profit organization whose hundreds of members are businesses, professional associations and local government groups dedicated to educating the public about ways to make our civil liability laws more fair, efficient, uniform and economical. Our goal is not, to be sure, of purely academic interest or motive, but arises from the practical vicissitudes of legal and economic life too frequently visited upon our members, especially litigation over who gets how much, from whom, and under what circumstances when unlawful conduct is charged. Toward achievement of our purpose, CJAC regularly petitions co-equal and coordinate branches of the federal and California

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[1] Counsel of record for all parties consent to the filing of this amicus brief. All counsel received notice at least 10 days before the filing date of the intention to file said amicus brief.

No counsel for a party authored this brief in whole or in part, and no counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person or entity other than amicus curiae, its members or its counsel made a monetary contribution to its preparation or submission.

[2] Formerly The Association for California Tort Reform ("ACTR").

governments to provide greater clarity and fairness to laws that intersect with and inform this objective.[3]

Amicus agrees with this Court's expressed concern in its recent reversal of another Ninth Circuit opinion that application of a "low" pleading threshold as to the "loss causation" element of a plaintiff's claim in a fraud class action like this one "tend[s] to transform a private securities action into a partial downside insurance policy." (*Dura Pharm., Inc. v. Broudo*, 544 U.S. 336, 347-48 (2005) ("*Dura*").) Despite the unfairness to defendants and the administration of justice of such a result, the Court in *Dura* nonetheless passed on addressing the issue of whether a higher pleading standard of specificity or particularity is required of future plaintiffs' loss causation pleadings because the plaintiffs there could not even meet the minimum threshold of "notice" pleading. Here, plaintiffs may have met the "bare-bones" pleading threshold but, as amicus contends and this case demonstrates, more should be required of them lest defendants continue to be deprived of a legitimate weapon to thwart securities fraud strike suits by plaintiffs and their counsel.

This case presents yet another opportunity for the Court to provide much needed certainty and clarity concerning the issue left unanswered by *Dura*: Does the Private Securities Litigation Reform Act of 1995

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[3] See, e.g., *Shell Oil Co. v. U.S.A.*, No. 07-1607; *Pacific Mut. Life Ins. Co. v. Haslip*, 499 U.S. 1 (1991); and *Browning-Ferris Industries of Vermont, Inc. v. Kelco Disposal, Inc.*, 492 U.S. 257 (1989).

(PSLRA)[4] require a more stringent pleading standard for "loss causation" than the low threshold found sufficient by the Ninth Circuit here – that the alleged facts "support a theory that is not facially implausible." (Petitioners' Appendix ("App.") 17a.) While the "plain language" of the PSLRA does not expressly answer this query, its statutory structure and intended purpose implicitly require that "loss causation" be pled with particularity just like scienter and misrepresentation. Guidance on this point now is precisely the type of gap-filling quasi-legislative roll the framers intended the Court provide.

BACKGROUND AND PROCEEDINGS BELOW

A. The Federal District Court's Decision Dismissing this Case

This case arises from dismissal by the federal district court of plaintiff investors' Fourth Amended class action complaint ("FAC") for "loss causation" resulting from alleged securities fraud by petitioner Gilead Sciences, Inc. The district court found that plaintiffs – persons who purchased or otherwise acquired Gilead stock between July 14, 2003 and October 28, 2003 (the "class period") – failed in their FAC allegations to satisfy the pleading requirements of the PSLRA and Federal Rules of Civil Procedure 12(b) and 9(b).

Specifically, allegations in the FAC focus on Gilead's announcements on July 14, and 31, 2003 of its financial results for the second quarter of 2003, and

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[4] Pub. L. No. 104-67, 109 Stat. 737.

the impact its premier product, Viread, had on those results. Viread is an antiretroviral drug used to treat HIV/AIDS, which Gilead introduced in 2001. In its announcements, Gilead gave an optimistic projection for its second quarter financial results, which it attributed to "strong sales growth" of Viread due to "broader prescribing patterns . . . as well as increases in U.S. wholesaler inventory . . .." (App. 22a.)

Gilead's July 31 announcement also contained warnings, reiterated in its Form 10-Q filed August 14, that its forward-looking statements were "subject to certain risks and uncertainties, which could cause actual results to differ materially." (*Id.* at 23a.) The Form 10-Q also disclosed a July 29, 2003 letter issued by the FDA, and made public by Gilead on August 7, warning Gilead about certain aspects of of its "off-label" promotional aspects for Viread. "Off-label marketing refers to the use for marketing purposes of information such as the result of clinical studies and other material on the uses of and the efficacy of an FDA-approved product that has not been approved by the FDA for inclusion in the product's package labeling." (*Id.* at 25a.)

When Gilead issued its July 31 press release, the company also held a conference call with analysts and investors, and through a corporate officer, explained that "a substantial inventory build occurred in the U.S. distributor channel during the second quarter as wholesalers anticipated the Viread price increase announced on June 27th. (*Id.*) "Based on U.S. inventory build up seen in the second quarter," the Gilead officer reported, "we anticipate Viread sales for the third quarter will be at or below the sales level recognized this second quarter;" and that "[w]e expect

these inventories to be drawn down to more normal levels during this quarter." (*Id.*)

Then on October 28, 2003, Gilead issued a press release announcing its financial results for the third quarter of 2003, which included net revenues of $194.1 million, and sales of Viread of $115.4 million. Gilead also stated that "after reviewing . . . prescription trends, . . . inventory data and actual Viread sales, [it] estimates there was approximately $33 to $37 million of inventory reduction by U.S. pharmaceutical wholesalers during the third quarter of 2003 following an equivalent inventory build during second quarter of 2003." (*Id.* at 24a.) The following day, Gilead's stock dropped $7.46 per share from $59.46 to close at $52. About one month later, Gilead's stock price recovered the entire drop experienced on October 29 and closed at $59.83 per share. (*Id.*)

According to the FAC, investors did not attribute much significance to the FDA letter warning Gilead about its off-label use of Viread. (*Id.* at 24a, 27a.) Plaintiffs claim that 75% to 95% of Viread sales were attributable to off-label promotion of Viread, and that this accounted for between $86.7 million and $109.82 million of Gilead's second quarter 2003 domestic sales. (*Id.*) Plaintiffs charge that Gilead maintained this misleading image of Viread long enough for the stock price to become inflated and for defendants to sell their shares before the FDA made their letter to Gilead public. (*Id.*)

The district court was unpersuaded that these allegations in the FAC sufficiently pleaded "loss causation," finding that they are simply "too attenuated." (*Id.* at 34a.) "The fundamental problem

with Plaintiffs' allegations is that they require the Court to make the unreasonable inference that a public revelation on August 8 caused a price drop three months later on October 28." (*Id* at 35a.) Moreover, "Plaintiffs' assertion that the FDA Warning Letter was the cause of the lower demand for Viread still does not establish a causal connection. Even if the FDA Warning Letter caused practitioners to reduce their Viread supply, Plaintiffs still fail to connect that with the drop in stock price." (*Id.*)

The district court concluded that "Plaintiffs have not adequately connected the disclosure of Gilead's off-label marketing and the drop in stock price in the FAC. Indeed, the evidence Plaintiffs have presented . . . only supports an inference that the market gave little or no weight to the FDA Warning Letter." (*Id.* at 39a, fn. 14.) Accordingly, the Court dismissed the FAC finding that "Plaintiffs have not adequately pled, under *Dura*, that the alleged misrepresentation proximately caused their loss." (*Id.*)

B. The Ninth Circuit's Opinion of Reversal

The appellate court reversed, stating the district court's "incredulity" was what animated its dismissal of the action rather than a facially inadequate complaint. If the district court could not make "the unreasonable inference that a public revelation on August 8 caused a price drop three months later on October 28," or found "a slowing increase in demand, alone, too speculative to . . . demonstrate loss causation," this was because the court was improperly acting as "a trier of fact." (*Id.* at 17a.) It is enough, the appellate court stated, that plaintiffs allege "facts to support a theory that is not facially implausible." (*Id.*)

In justifying its reversal, the appellate opinion states that "[a] limited temporal gap between the time a misrepresentation is publicly revealed and the subsequent decline in stock value does not render a plaintiff's theory of loss causation per se implausible." (*Id.* at 19a.) Moreover, though obviously the market did not react immediately to Gilead's corrective disclosure about the FDA Warning Letter, it did react to Gilead's October 28, 2003 release of "less-than-expected revenues," which arguably resulted "from the reduction in wholesalers' Viread inventories," which analysts ascribed to "lower-end user demand" that, "in turn," was allegedly "caused by the Warning Letter." (*Id.*)

The appellate opinion characterizes as "erroneous" the district court's conclusion "that a slowing increase in demand is too speculative to establish loss causation." (*Id.*) Why? Because "[h]ad the investors alleged that the Warning Letter eliminated all sales resulting from off-label marketing, it would be very unlikely that demand would continue to increase, since the complaint asserts that 75% to 95% of sales were caused by off-label marketing." No matter that plaintiffs did not allege that, "we see no reason why the court cannot proceed to the evidentiary stages to determine the extent of the Warning Letter's impact on the growth of demand for Viread." (*Id.* at 20a.)

SUMMARY OF ARGUMENT

The Ninth Circuit's opinion in this case that "loss causation" in a securities fraud action is satisfied at the pleading stage so long as the complaint provides enough information to show that the theory upon which it is based is "not facially implausible" is at odds

with other circuits and the PSLRA. The result is that, in the Ninth Circuit now, plaintiffs claiming "loss causation" need not provide any factual basis to show that their loss occurred after the alleged fraud became generally known to the market or, even if it did, that they are capable of isolating the fraud from other confounding and contributing factors.

This disparity between the lax "not per se implausible" pleading standard of the Ninth Circuit for "loss causation" and the more heightened pleading standards of numerous other circuits, creates the very "confusion worse confounded" situation that the PSLRA was enacted to avoid. Unless and until the Court acts to provide uniformity and clarity as to the proper pleading standard applicable to "loss causation" claims in securities fraud, plaintiffs will understandably forum shop to file in the least restrictive jurisdictions, increasing the volume of groundless lawsuits filed there and the attendant expense and discovery abuse which the PSLRA intended to prevent.

This case provides a unique opportunity for the Court to provide the clarity and uniformity necessary to correct the confusion in the circuits over what standard courts are to apply as gatekeepers in screening securities fraud lawsuits.

REASONS FOR GRANTING THE WRIT

I. THE NINTH CIRCUIT'S "NOT *PER SE* IMPLAUSIBLE" STANDARD OF PLEADING WHEN "LOSS CAUSATION" IS ALLEGED IN SECURITIES FRAUD COMPLAINTS CONFLICTS WITH OTHER CIRCUITS WHICH REQUIRE "PARTICULARITY" OR "HEIGHTENED PLEADING."

The opinion in this case exacerbates what has become a "most troublesome question"[5] over which the Circuits are divided – What is the proper pleading standard to apply in federal securities fraud actions based on "loss causation"? The answer to this query – whether a heightened or particularized standard, or a lax, bare-bones "notice" standard applies – is important because it determines whether courts can effectively function as "gatekeepers" to nip meritless securities actions before discovery costs burgeon out of control and discovery abuse occurs. (See, *e.g.*, *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, ___ (2007). Indeed, "[f]ew issues in civil procedure jurisprudence are more significant than pleading standards, which are the key that opens access to courts" and keeps them from being flooded with groundless litigation. (*Phillips v. County of Allegheny*, 515 F.3d 224, 230 (3d Cir. 2008).

In re Merck & Co. Sec. Litig., 432 F.3d 261, 268 (3d Cir. 2005), for instance, affirmed dismissal of a securities fraud class action against a corporation and its individual officers because the complaint did not

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[5] *Linkletter v. Walker*, 381 U.S. 618, 620 (1965).

satisfy the "heightened pleading" standard that Circuit holds applicable for securities fraud litigation. "To make out a securities fraud claim under section 10(b), a plaintiff must show that . . . 'the plaintiff's reliance on the defendant's misstatement caused him or her injury.'" (*Id. at 268,* quoting *Cal. Pub. Employees' Ret. Sys. v. Chubb Corp.*, 394 F.3d 126, 143 (3d Cir. 2004)). "These requirements are heightened by the PSLRA, which requires that the complaint 'state *with particularity* all facts on which [plaintiff's] belief is formed.'" (*Id.*; alteration in original, quoting 15 U.S.C. § 78u-4(b)(1) (2000).) (*Accord*: *GSC Partners CDO Fund v. Washington*, 368 F.3d 228, 236 (3d Cir. 2004).)

Similarly, *Plotkin v. IP Axess Inc.*, 407 F.3d 690, 696 (5th Cir. 2005), another securities fraud action, holds that to demonstrate a 10b-5 violation, a plaintiff must prove that the defendant proximately caused the plaintiff's injury. (407 F.3d at 696.) The PSLRA, according to the *Plotkin* opinion, "requires a securities fraud plaintiff . . . to plead these substantive [10(b)] elements with *particularity*. The PSLRA's particularity requirement incorporates, at a minimum, the pleading . . . under Federal Rule of Civil Procedure 9(b)." (*Id.*, emphasis added, citation omitted.)

Finally, as Petitioners show, the Second, Fourth and Eighth Circuits also demand "a heightened degree of factual specificity in pleading loss causation" in securities fraud claims (Petition ("Pet.") 18); and "a plethora of recent cases [in federal district courts] have applied heightened pleading standards to loss causation." (Brandon C. Helms, *Note: The Supreme Court's Dura Decision Unfortunately Secures a Brighter Future for 10b-5 Defendants*, 56 DEPAUL L. REV. 189, 218 (2006).) These five circuits, then,

squarely contradict the Ninth Circuit's holding in this case that all a plaintiff need plead to pass muster in a securities fraud action for "loss causation" is "facts to support a theory that is not facially implausible." (App. 17a.) Other Circuits may, to be sure, more closely align themselves with the Ninth in their tolerance toward what is required by way of a pleading standard for securities fraud; and plaintiffs will likely bring them to the Court's attention. The point here is not to count heads, however, but to recognize that a genuine conflict between the Circuits exists over this important issue, and these deep differences have drawn the attention of courts and commentators. "[N]otwithstanding efforts to constrain judicial decision-making through articulation of a seemingly-specific heightened pleading standard, interpretive variance by the courts has been marked." (Lonny S. Hoffman, *Burn up the Chaff with Unquenchable Fire: What Two Doctrinal Intersections Can Teach Us about Judicial Power over Pleadings*, 88 *B.U. L. REV.* 1217, 1260 (2008).)[6]

Given the Ninth Circuit's demonstrated willingness in this case to extrapolate to the stars, building inference upon speculative inference in an attempt to puff the FDA Warning Letter into a "plausible" *cause* for the October drop in Gileads' stock price, it is

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[6] See also Joseph A. Grundfest & A.C. Pritchard, *Statutes with Multiple Personality Disorders: The Value of Ambiguity in Statutory Design and Interpretation*, 54 *STAN. L. REV.* 627, 633-34 (2002). The authors examined thirty-three courts of appeals decisions and one hundred sixty-seven district court decisions and concluded that Congress' ability to draft the pleading standard ambiguously as a means of legislative compromise prevailed over the courts' abilities to interpret the pleading standard uniformly.

difficult to imagine a complaint that would not satisfy its lax pleading standard. When there is a gulf in pleading hurdles as great as that shown between the Ninth and at least five other circuits, however, the consequence to the administration of justice is dire. Absent a uniform pleading standard for securities fraud, jurisdictions with less restrictive standards will understandably attract, like iron filings to a magnet, a disproportionate share of securities fraud litigation. "Heightened pleading standards in securities fraud actions contribute to a 39.1% dismissal rate at this early litigation phase." (Elizabeth Chamblee Burch, *Securities Class Actions as Pragmatic ex Post Regulation*, 43 *GA. L. REV.* 63, 80 (2008).) Looser pleading standards make it easier to evade the court as "gatekeeper" and yield recovery for dubious claims. See Robert J. Giuffra Jr., *CEOs Beware: The Strike Suit Lives*, *WALL ST. J.*, Sept. 13, 1999, at A45 (noting that because of the circuit division, "the regulation of the securities markets will become a game of roulette, with the outcome turning on whether a securities class action is filed in New York or Silicon Valley.").

The Court's guidance is sorely needed to bring uniformity and certainty to the issue of what pleading standard applies in securities fraud claims for "loss causation." Only with that guidance, and only if it provides for a more particularized standard that permits the weeding out of groundless claims, can strike suits, forum shopping, needless discovery costs and discovery abuse be curtailed at the earliest and most economic opportunity.

II. THE PSLRA AND SOUND PUBLIC POLICY FAVOR A "PARTICULARIZED" OR "HEIGHTENED" PLEADING STANDARD IN SECURITIES FRAUD CLAIMS FOR "LOSS CAUSATION" INSTEAD OF THE "NOT PER SE IMPLAUSIBLE" STANDARD APPLIED IN THIS CASE.

When Congress passed the PSLRA it provided for heightened pleading requirements in federal securities fraud actions under Rule 10b-5. (*See* 15 U.S.C. § 78u-4(b)(1).) More specifically, sections 21D(b)(1) and (2) explicitly created heightened pleading requirements for the misrepresentation and scienter elements of a Rule 10b-5 claim. While the provision in the PSLRA that addressed "loss causation" did not expressly call for the application of a heightened pleading standard to plaintiffs' loss causation pleadings,[7] reading the PSLRA to add the loss causation element and then excluding it from the new pleading standard is illogical and counter to the legislation's purpose.

The Court has the opportunity in this case to hold that the PSLRA implicitly requires loss causation to be pled with particularity just like scienter and misrepresentation. Indeed, this is precisely the type of role the framers intended the Court to exercise.

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[7] *See* 15 U.S.C. § 78u-4(b)(4) (2000) (stating that "[i]n any private action arising under this chapter, the plaintiff shall have the burden of proving that the act or omission of the defendant alleged to violate this chapter *caused the loss for which the plaintiff seeks to recover damages*" (emphasis added)).

> It is now a commonplace that courts, not only of common law jurisdictions but also those which have codified statutory law as their base, participate in the lawmaking process. The commonplace, for which the Holmeses and the Cardozos had to blaze a trail in the judicial realm, assumes the rightness of courts in making interstitial law, filling gaps in the statutory and decisional rules, and at a snail-like pace giving some forward movement to the developing law.[8]

Indeed, the Court recently adjudicated in precisely this fashion when it defined more clearly what the 104th Congress meant by "strong inference" when it used that term as part of a more stringent pleading standard for scienter in the PSLRA. *See Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, ___ (2007). The Court can and should act similarly here in recognizing that the heightened pleading standards in the PSLRA were putatively modeled after the Second Circuit's standard, which required more than notice pleading for loss causation at the time the PSLRA was drafted. *See* S. REP. NO. 104-98, at 7 (1995) (Conf. Rep.), *reprinted in* 1995 U.S.C.C.A.N. 679, 686 (stating that the purpose of the original PSLRA bill was, "[to clarify] the *pleading requirements* for bringing securities fraud claims by adopting a standard modelled [sic] on that currently applied by the United

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[8] Norman J. Singer, *STATUTES AND STATUTORY CONSTRUCTION* § 5A:2 (6th ed. 2002).

States Court of Appeals for the Second Circuit, the leading circuit court in [the] area." (emphasis added).[9]

Respected jurists and legal scholars agree that the Court must, at the very least, look at the problem a piece of legislation purports to address and construe ambiguous language within that statute to further that purpose most effectively.

> [I]f the words used by the legislature are open to more than one [meaning] – as is often the case in disputes . . . that reach the courts – the court must look harder and longer and consider the legislative purpose behind the statute, the legislative history, and perhaps the canons of construction. Whether 'intent' or 'purpose' or some other similar measure serves as the benchmark, the traditional approach assumes a discoverable legislative design, and the court's

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[9] As Petitioners explain, "the Second Circuit has applied Rule 9(b) to loss causation in the RICO context, holding that a plaintiff 'must allege loss causation with *sufficient particularity* such that we can determine whether the factual basis for the claim, if proven, could support an inference of proximate cause.'" Pet. 18, emphasis added, citing *First Nationwide Bank v. Gelt Funding Corp.*, 27 F.3d 763, 770-72 (2d Cir. 1994). See also Devin F. Ryan, Comment, *Yet Another Bough on the "Judicial Oak": The Second Circuit Clarifies Inquiry Notice and Its Loss Causation Requirement under the PSLRA in Lentell v. Merrill Lynch & Co.*, 79 *ST. JOHN'S L. REV.* 485, note 34, at 489 (2005) (observing that the Second Circuit announced in *Lentell v. Merrill Lynch & Co.*, 396 F.3d 161 (2d Cir. 2005), *cert. denied*, 546 U.S. 935 (2005) that loss causation must be plead to a higher standard than notice pleading, and that the standard to which it must be pled is similar to the one subsequently proscribed by Congress via the PSLRA for scienter and misrepresentation).

> cardinal obligation remains to identify and execute that design . . .. [T]he traditional approach to statutory interpretation, . . . focuses judicial attention on the dispositive 'legislative intent.' . . . [T]his conception gives judges clear marching orders. If the words of the statute unambiguously reflect legislative intent, the court should go no further.[10]

"[A]lthough the [PSLRA] was intended to provide a uniform pleading standard in securities class action litigation, courts have issued splintered opinions regarding the proper standards." (R. Tyler Hand, *Note: the Private Securities Litigation Reform Act of 1995: Heightened Pleading Standards in Class Action Litigation*, 26 *AM. J. TRIAL ADVOC.* 685, 690 (2003).) Ambiguity about the pleading standard required for "loss causation" by the PSLRA breeds uncertainty and, as the opinions from the Circuits show, conflict. This defeats the purpose of the legislation, leading to forum shopping amongst plaintiffs for jurisdictions with lax pleading standards and a more inviting climate for groundless strike-suits the PSLRA was enacted to curtail. This vexing situation calls for the Court to interpret and apply the PSLRA in the context of its clear purpose,[11] providing needed certainty, clarity and uniformity.

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[10] Jane S. Schecter, *Metademocracy: The Changing Structure of Legitimacy in Statutory Interpretation*, 108 *HARV. L. REV.* 593, 594-95 (1997).

[11] Interpretation . . . depends on reading the whole statutory text, *considering the purpose* and context of the statute, and consulting any precedents or authorities that inform the analysis. *Dolan v. Postal Service*, 546 U.S. 481, 486 (2006) (emphasis added).

CONCLUSION

For all the aforementioned reasons, the Court should grant the petition for review filed by Gilead and its top officers.

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IN THE

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v.

TRENT ST. CLARE, *et al.*,
Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

BRIEF FOR FORMER SEC COMMISSIONERS AND OFFICIALS AND LAW AND FINANCE PROFESSORS AS AMICI CURIAE IN SUPPORT OF PETITIONERS

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BRIEF FOR FORMER SEC COMMISSIONERS AND OFFICIALS AND LAW AND FINANCE PROFESSORS AS AMICI CURIAE IN SUPPORT OF PETITIONERS

INTEREST OF AMICI CURIAE[1]

Amici curiae are former Commissioners of the Securities and Exchange Commission (SEC) and professors of law and finance whose fields of expertise include securities regulation, class-action practice, and law and

[1] No counsel for a party authored this brief in whole or in part, and no persons or entities, other than *amici*, their members, or their counsel, made a monetary contribution to the preparation or submission of this brief. Letters from the parties consenting to the filing of this brief are on file with the Clerk.

economics. *Amici* have devoted substantial parts of their professional careers to implementing, drafting, and studying the federal securities laws, including how those laws should be interpreted to ensure protection of investors and promotion of efficiency, competition, and capital formation.

This brief reflects the consensus view of the *amici*, all of whom believe that the decision below should be reversed. Each individual *amicus* may not, however, endorse every argument presented herein. The former Commissioners and professors joining this brief as *amici*, listed alphabetically, are:

The Honorable Charles C. Cox, who served as a Commissioner of the SEC from 1983 through 1989, and as Chief Economist of the SEC from 1982 through 1983;

The Honorable Joseph A. Grundfest, who served as a Commissioner of the SEC from 1985 through 1990 and who is the William A. Franke Professor of Law and Business at Stanford Law School, Co-Director of the Rock Center on Corporate Governance at Stanford University;

Professor Allen Ferrell, who is the Greenfield Professor of Securities Law at Harvard Law School;

The Honorable Philip R. Lochner, Jr., who served as a Commissioner of the SEC from 1990 through 1991.

Simon M. Lorne, who served as General Counsel of the SEC from 1993 to 1996 and is an adjunct professor at the NYU School of Law and NYU's Stern School of Business;

Professor Larry E. Ribstein, who is the Mildred Van Voorhis Jones Chair in Law at the University of Illinois College of Law;

Professor Kenneth E. Scott, who is the Ralph M. Parsons Professor of Law and Business emeritus at Stanford Law School.

INTRODUCTION AND SUMMARY OF ARGUMENT

In this case, the Ninth Circuit set a standard for pleading loss causation that is inconsistent with the teachings of this Court and with the decisions of other circuits. Petitioners have highlighted a number of problems with that decision that independently support review, including but not limited to the split between circuits concerning the standard for alleging loss causation. *Amici* write separately to illuminate one feature of the Ninth Circuit's decision that merits this Court's particular attention: its misunderstanding of the concept of an efficient market, and how that concept bears upon loss causation.

Although there are different views about how securities markets operate and how efficient they are, the central concept *for legal purposes* is that the market price of a security swiftly incorporates all available material information (including *mis*information). This Court ruled more than 20 years ago, for example, that individual proof of reliance on an issuer's misstatement (which if required would defeat class certification) could be replaced by the rebuttable presumption that each class member relied on market price and that this price in turn reflected the misstatement. *Basic, Inc.* v. *Levinson*, 485 U.S. 224, 248 (1988). By its very terms, that theory of reliance works only if the price incorporates the misstatement quickly, at the beginning of the class period. Similarly, if the efficient market theory is also the basis for plaintiffs' theory of loss causation, that theory works only when the market reacts (and the stock price drops) promptly in response to a statement

correcting the previous misstatement. Accordingly, the "efficient market" theory can be deployed only if the market at issue is shown to incorporate material information into the price of a stock relatively quickly. Courts of appeals outside the Ninth Circuit have applied the theory in this form.

The Ninth Circuit, by contrast, has now endorsed a loss causation theory attributing a price drop in October to information disclosed in August. Its decision fundamentally misconstrues the efficient market theory, and ventures far from route taken by other circuits that see large numbers of securities cases.[2] Indeed, in *Gilead* the Ninth Circuit for the second time disclaimed the need for temporal proximity between disclosure of material information and an efficient market's reaction. Pet. App. 18a-19a. The opinion concludes that it is facially plausible that a market may be efficient yet still take months to incorporate startling new information into a stock price. *Id.* The Ninth Circuit thus upheld a complaint that, while alleging the market was efficient in order to support class treatment, nevertheless theorizes that a disclosure in August took two months to effect a drop in stock price.

By giving its blessing to this strikingly inefficient "efficient market," the Ninth Circuit reinforces its con-

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[2] A recent study shows that 25.5 percent of all securities fraud class actions since 1996 have been filed in the Ninth Circuit *See* Cornerstone, *Securities Class Action Filings 2008: A Year In Review*, Stanford Law School Securities Class Action Clearinghouse, *at* http://securities.stanford.edu/clearinghouse_research/2008_YIR/20090106_YIR08_Full_Report.pdf, fig. 21). The five other circuits addressed in Part B, *infra*, (the 1st, 2d, 5th, 6th, and 7th Circuits) account for 53.6 percent of all such actions. *See id.*

flict with other circuits and establishes a precedent for a weakened loss causation pleading requirement that is inconsistent with this Court's decision in *Dura*.

Amici are concerned that *Gilead*, by fundamentally misapplying the efficient market theory, undermines the theoretical basis for "fraud on the market" class actions, degrades the requirement of a causal link between a corrective disclosure and a stock drop, and weakens pleading standards to the point where mere speculation can sustain a class action complaint. To resolve the split between the Ninth Circuit and five other courts of appeals, preserve the integrity of the efficient market theory as recognized by this Court in *Basic*, and ensure its consistent application in nationwide securities class actions, this Court should grant the petition and reverse the decision below.

ARGUMENT

THE COURT SHOULD CORRECT THE NINTH CIRCUIT'S MISAPPLICATION OF THE EFFICIENT MARKET HYPOTHESIS AND THE RESULTING WEAKENING OF THE STANDARDS FOR PROVING LOSS CAUSATION IN THAT CIRCUIT

A. Most Circuits Accept The Presumption That An "Efficient Market" Rapidly Incorporates New Material Information Into Stock Prices

When this Court determined that class plaintiffs could rely on the efficient market theory (and therefore on the fraud on the market theory of reliance, on which modern securities class action litigation is based), the Court "did not intend conclusively to adopt any particular theory of how quickly and completely ... information is reflected in market price." *Basic, Inc.* v. *Levinson*, 485 U.S. 224, 248 n. 28 (1988). But it did recognize that the point of the theory was to create a presumption that all persons who purchased or sold a stock within a

specified period relied on certain information that was reflected in the price of that stock. *See id.* at 247. This presumption makes sense when and only when the market reacts promptly to issuer misstatements and later corrections. *See id.* (In the absence of this presumption, securities fraud cases generally could not proceed as class actions because proof of reliance on an individual basis would overwhelm any common questions of law and fact. *See id.* at 242.)

Since *Basic*, the courts of appeals have repeatedly acknowledged that an efficient market not only incorporates information into stock prices, but does so very quickly. "Evidence that unexpected corporate events or financial releases cause an ***immediate*** response in the price of a security has been considered ... 'the ***essence*** of an efficient market and the foundation for the fraud on the market theory.'" *Teamsters Local 445 Freight Division Pension Fund* v. *Bombardier, Inc.*, 546 F.3d 196, 207 (2d Cir. 2008) (citation omitted; emphasis added) (affirming denial of class certification where price did not reflect immediate reaction to adverse information). The presumption of classwide reliance does not work unless the market incorporates new information rapidly, so that every purchaser (or every seller) after a given disclosure can be presumed to have relied indirectly on the same incorporated information.

One court of appeals described an efficient market as one in which "market price responds so quickly to new information that ordinary investors cannot make trading profits on the basis of such information." *In re PolyMedica Corp. Sec. Litig.*, 432 F.3d 1, 19 (1st Cir. 2005). Other courts have articulated the efficient market hypothesis in terms of an "immediate" or "rapid" incorporation of new information. *See, e.g., Freeman* v. *Laventhol & Horwath*, 915 F.2d 193, 199 (6th Cir. 1990)

("An efficient market is one which rapidly reflects new information in price."); *West* v. *Prudential Sec. Inc.*, 282 F.3d 935, 938 (7th Cir. 2002) ("[M]arkets are efficient in the sense that they rapidly adjust to all public information ...[.] This approach has the support of financial economics as well as the imprimatur of the Justices: few propositions in economics are better established than the quick adjustment of securities prices to public information."); *Gariety* v. *Grant Thornton LLP*, 368 F.3d 356, 367 (4th Cir. 2004) ("[I]n an efficient market, 'the market price has integrity[;] ... it adjusts rapidly to reflect all new information.'" (citations omitted)); *Unger* v. *Amedisys Inc.*, 401 F.3d 316, 324 (5th Cir. 2005) ("In an efficient market, where information is nearly perfect, material misstatements alter a stock's price almost immediately."); *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1425 (3d Cir. 1997) (an efficient market incorporates information "immediately"; information that did not move the market when disclosed was not actionable). Whether using the words "prompt," "immediate," or "rapid," or otherwise, the courts of appeals other than the Ninth Circuit have taken the logically correct, common-sense view that an efficient market is one that *quickly* incorporates information into stock prices.

B. The Ninth Circuit's Application Of The Efficient Market Hypothesis Is Fundamentally Flawed And Inconsistent With The Standards Of Other Circuits

1. The Ninth Circuit has now twice disavowed any need for an efficient market to react quickly to material information

The complaint in *Gilead* (like virtually all class actions alleging violations of Rule 10b-5) invokes the fraud on the market presumption. That presumption—

that purchasers of Gilead stock relied indirectly on defendants' alleged misstatements when they relied on the market price—necessarily assumes that the market "efficiently" incorporates available material information into the price. *See e.g.*, *Basic*, 485 U.S. at 241-242. But the Ninth Circuit ruled that even in an efficient market, "[a] limited temporal gap between the time a misrepresentation is publicly revealed [i.e., corrected] and the subsequent decline in stock value does not render a plaintiff's theory of loss causation per se implausible." *See* Pet. App. 19a. In *Gilead*, the "limited gap" was two months: a corrective disclosure of off-label marketing activity in August could have resulted in a stock decline at the end of October, or so the court held.

That cannot be right. The problem is not a matter of the *definition* of market "efficiency." Whatever the label, if there can be two months between an issuer statement and its effect on market price, then investors relying on market prices are *not* all indirectly relying on the same underlying misinformation, and reliance cannot be resolved on a classwide basis.

Gilead marks the second time that the Ninth Circuit has held that a market can be sufficiently efficient to support a presumption of reliance on stock price even when there is no evidence of swift reaction to disclosure of a material fact. Indeed, five years ago, the Ninth Circuit held that a fact could be material even if its disclosure did not result in a swift stock price reaction. *See No. 84 Employer-Teamster Joint Council Pension Trust Fund* v. *America West Holding Corp.*, 320 F.3d 920, 934 (9th Cir. 2003). Hence, the Ninth Circuit has now applied the view that a market need not react quickly in order to be efficient in the context of both materiality and loss causation.

2. The Ninth Circuit's view is inconsistent with the operation of an efficient market and with this Court's guidance on loss causation

The Ninth Circuit's ruling in *Gilead* would cripple the efficient market hypothesis. Regardless of whether an efficient market acts "immediately," as some argue, or merely "rapidly," a multi-month delay in response to a supposedly shocking disclosure is not consistent with market efficiency under any reasonable definition, nor (more importantly) is it consistent with the legal *application* of the market efficiency concept to allow proof of reliance on a classwide basis. *Gilead*'s approach runs contrary to the basic assumptions under which class litigants seek to establish reliance and loss causation in securities cases, and thus puts the Ninth Circuit out of step with both the logic of the law and the prevailing views of other circuits.

On the most basic level, the classwide presumption of reliance cannot apply unless securities markets react rapidly to alleged material misinformation. If a stock's price does not reflect material information when that information is disclosed, putative class members cannot be presumed to have relied upon that information via the stock price. In the absence of such a presumption, individual issues of reliance will predominate over class-wide issues. *See Basic*, 485 U.S. at 242. If a stock price requires an extended period to incorporate available information, individual class members will be differently situated depending on how much of the incorporation process had been completed at the time of each purchase. By allowing that such a market could still be deemed "efficient," the Ninth Circuit holdings thus call the entire presumption of reliance into question—undermining class-wide treatment of Rule 10b-5 claims.

Built on this flawed first principle, the *Gilead* decision is inconsistent with this Court's decision in *Dura* with respect to loss causation. *Dura* requires plaintiffs to allege and ultimately prove a causal nexus between disclosure of misconduct and their loss damages, typically by showing that price declined when a corrective disclosure was made or corrective information was otherwise revealed. *See Dura Pharms., Inc.* v. *Broudo*, 544 U.S. 336, 342-343 (2005) (discussing factors that may cause decline in stock price); *see also, e.g., Greenberg* v. *Crossroads Sys. Inc.*, 364 F.3d 657, 666 (5th Cir. 2004) (holding that to invoke the fraud on the market theory plaintiffs must prove loss causation by showing that stock price dropped upon disclosure of alleged fraud and was not attributable to other factors). A market that reacts swiftly to corrective disclosures can demonstrate a strong causal nexus between the previously undisclosed misconduct and the distortion of market price that harmed investors. But the theory, and the possibility of showing harm, evaporate if the market is not *expected* to react swiftly to information that changes the "total mix of information" available to investors. *Basic*, 485 U.S. at 231. If there is no price reaction for two months, then the price decline cannot be tied to the corrective disclosure and the underlying misconduct, as opposed to the several other factors to which *Dura* alludes. *See* 544 U.S. at 343.[3]

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[3] The *Gilead* opinion also suffers from a basic internal inconsistency by endorsing respondents' allegations that the underlying market was efficient *and* that it did not respond to material information for a period of months. It is hard to see how a case with such inherent contradictions could be permitted to proceed on a classwide basis.

If *Gilead* were accepted and incorporated uncritically by district courts, there would be few limits on the kinds of harm that a securities plaintiff could predicate on any given corrective disclosure. As long as a stock's price drops at some point after disclosure of alleged misconduct—no matter how many independent events have occurred between the disclosure and the stock drop—the case could still proceed past the pleading stage based on allegations of a delayed reaction.

The Court should correct the Ninth Circuit's fundamentally incorrect view of the law on such a basic concept. The Ninth Circuit has been and is certain to continue to be a major securities litigation venue, and a source of some of the most important decisions in the field.[4] Given the level of securities activity in the circuit, *Gilead*'s standard could fundamentally shift the playing field for parties, waste judicial resources on analysis unbound by law or logic, and spell the end of the efficient market hypothesis, in theory as well as practice.

C. A Complaint Cannot Establish Loss Causation By Asserting A Connection Between A Material Disclosure And A Facially Unrelated Disclosure Several Months Later

Perhaps recognizing the difficulties with its implementation of the efficient market theory, the court of appeals notes in *Gilead* that the stock declined immediately after the October earnings announcement, which

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[4] *See, e.g.*, Cornerstone, *Securities Class Action Filings 2008: A Year In Review*, Stanford Law School Securities Class Action Clearinghouse, *at* http://securities.stanford.edu/clearinghouse_research/2008_YIR/20090106_YIR08_Full_Report.pdf, at 20 (comparing class filings by circuit).

respondents allege "reflected" the impact of previously disclosed off-label marketing practices. *See* Pet. App. 19a. It is not clear why the Ninth Circuit saw a need to address this point at all given its holding that "[a] limited temporal gap" between a disclosure and a stock drop "does not render a plaintiff's theory of loss causation per se implausible." *See id.* However, to the extent the Ninth Circuit intended to buttress its ultimate holding by endorsing respondents' late-raised theory that it was the October announcement and not the August announcement that "corrected" this alleged misinformation, the opinion runs squarely counter to this Court's guidance in *Dura* and *Twombly*. *See Dura*, 544 U.S. at 343; *Bell Atlantic Corp.* v. *Twombly*, 127 S. Ct. 1955, 1965 (2007).

This Court has explained that "something beyond the mere possibility of loss causation must be alleged, lest a plaintiff with a largely groundless claim be allowed to take up the time of a number of other people, with the right to do so representing an *in terrorem* increment of the settlement value." *Twombly*, 127 S. Ct. at 1966 (internal quotation marks omitted). To that end, *Dura* requires plaintiffs to connect a stock decline to revelation of an alleged fraud, rather than to a different factor. *See* 544 U.S. at 343. Loss causation thus requires evidence that the market became aware of alleged misinformation, and that the stock price fell in response. *See id.* at 342-343.[5] This, in a securities-fraud

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[5] *See also, e.g.*, Ferrell & Saha, *The Loss Causation Requirement for 10b-5 Causes of Action: The Implications of* Dura Pharmaceuticals v. Broudo, 63 Bus. Lawyer 163, 173 (2007) ("[W]ithout a concrete reason to link the negative stock market reaction associated with [a disclosure] ... to the removal of the inflation in the stock price caused by the actionable misconduct[,] ... loss causation

context, is a component of the general requirements of *Twombly* that "factual allegations must be enough to raise a right to relief above the speculative level," *Twombly*, 127 S. Ct. at 1965, and that plaintiffs provide "enough facts to state a claim to relief that is plausible on its face," *id.* at 1974.

In combination, these decisions dictate that securities plaintiffs cannot simply pick a disclosure at some point before a price drop and ask the court to assume that this disclosure had something to do with that price drop, no matter how facially unrelated the two may be, because the price drop was allegedly a "realization" of the impact of the earlier disclosure. *See, e.g., Metzler Inc. GmbH* v. *Corinthian Coll., Inc.*, 540 F.3d 1049, 1064 (9th Cir. 2008) (dismissing claim that, *inter alia*, did not allege facts showing that announcement precipitating stock drop had disclosed the alleged fraud and rejecting fact-free assertions that earnings announcement caused market "realization" of the impact of a previously announced problem). As the Ninth Circuit itself recognized:

> So long as there is a drop in a stock's price, a plaintiff will always be able to contend that the market "understood" a defendant's statement precipitating a loss as a coded message revealing the fraud. Enabling a plaintiff to proceed

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is lacking."); Ribstein, *Fraud on a Noisy Market*, 10 Lewis & Clark L. Rev. 137, 160-161 (2006) ("[A] corrective disclosure arguably demonstrates how much the truth affects the price, enabling the court to determine by 'backward induction' how the company would have performed ... if the market had known the truth.... [T]here is no evidence [of causation] as reliable as the backward induction method.").

> on such a theory would effectively resurrect what *Dura* discredited—that loss causation is established through an allegation that a stock was purchased at an inflated price."

Id. at 1064.

That is exactly what happened here. In *Gilead*, the statement that triggered a stock price decline (the October announcement) was an earnings release that, *inter alia*, revised wholesaler inventory estimates. The Ninth Circuit accepts respondents' attenuated claim that this announcement was actually a coded but dramatic revelation of the impact of off-label marketing that had been disclosed months before—and that the stock drop was due to a sudden realization by the market of the allegedly high fraction of sales due to off-label marketing, rather than to concerns regarding wholesaler inventories. *See* Pet. App. 16a-17a; Pet. 9-10. But the opinion does not identify any statement disclosing the fraction of Company revenue attributable to off-label marketing—the key allegedly material fact that was allegedly undisclosed. *Compare, e.g., In re Williams Sec. Litig.-WCG Subclass*, --- F.3d ---, 2009 WL 388048, at *8 (10th Cir. 2009) (true "corrective" disclosure must relate to alleged misrepresentation rather than other negative information). Nor does it identify any fact suggesting that the market understood the announcement related to off-label marketing. Instead, the opinion assumes that the October announcement was a tacit acknowledgment of the impact of off-label marketing, and finds that because respondents' theory to that effect is "not per se implausible," it is sufficient to plead loss causation. Pet. App. 19a.

Gilead conflicts sharply with the teachings of *Dura* and *Twombly*. By endorsing respondents' theory de-

spite the lack of factual allegations that substantiate that theory, *Gilead* allows pleading by speculation—precisely what *Twombly* forbids. *See Twombly*, 127 S. Ct. at 1964-1965. This hollow standard "would permit a plaintiff with a largely groundless claim to simply take up the time of a number of other people, with the right to do so representing an in terrorem increment of the settlement value, rather than a reasonably founded hope that the [discovery] process will reveal relevant evidence"—the exact situation that *Dura* rejected. *See Dura*, 544 U.S. at 347 (internal quotation marks omitted). In keeping with *Dura* and *Twombly*, other circuits have refused to accept speculation of this kind to salvage otherwise deficient allegations. *See* Pet. 3-4 (citing authority). *Amici* respectfully submit that this Court should not permit one Circuit—particularly a circuit with as active a securities docket as the Ninth—to apply such an anomalous standard to loss causation pleadings.

D. This Court Should Take This Opportunity To Clarify The Efficient Market Theory's Operation And Effect On Loss Causation Pleadings

There is no reason for any court to entertain a Rule 10b-5 complaint that relies on the efficient market hypothesis for purposes of pleading elements of class certification but cannot identify a stock price decline proximately following disclosure of the alleged fraud. If a disclosure causes a decline in an efficient market, it will do so promptly. If an allegedly "corrective" disclosure does not promptly cause a price decline, then there is no reason to believe that there was material misinformation in the "total mix" of information available to investors. The Court thus should use this case to confirm that efficient markets, by definition and by the as-

sumptions inherent in the fraud on the market theory, react promptly to new material information.

This case further provides an example of speculative pleading tactics that highlight, rather than conceal, the weaknesses in a lawsuit. It is not be difficult for a plaintiff with a legitimate claim to identify a corrective statement that swiftly precipitates a price decline. In the current market, virtually any issuer can be victimized by a suit based on summary claims that current stock declines reflect a market "realization" of the impact of previously disclosed problems, even if the disclosure were months in the past. The Court should not countenance such a result.

CONCLUSION

This case presents an ideal opportunity for the Court to confirm the implications an efficient market carries for loss causation allegations, and to guide lower courts in analyzing such allegations. The Court therefore should grant the petition.

Respectfully submitted.

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In The
Supreme Court of the United States

GILEAD SCIENCES, INC., et al.,

Petitioners,

v.

TRENT ST. CLARE, et al.,

Respondents.

On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Ninth Circuit

BRIEF OF *AMICI CURIAE* NATIONAL ASSOCIATION OF MANUFACTURERS AND CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA IN SUPPORT OF PETITIONERS

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INTEREST OF *AMICI CURIAE*[1]

The National Association of Manufacturers ("NAM") is the nation's largest industrial trade association, representing small and large manufacturers in every industrial sector and in all 50 states. The NAM's mission is to enhance the competitiveness of manufacturers by shaping a legislative and regulatory environment conducive to U.S. economic growth and to increase understanding among policymakers, the media and the general public about the vital role of manufacturing to America's economic future and living standards.

The Chamber of Commerce of the United States of America ("the Chamber") is the world's largest business federation, representing an underlying membership of more than 3,000,000 businesses and organizations of all sizes. Chamber members operate in every sector of the economy and transact business throughout the United States, as well as in a large number of countries around the world. A central function of the Chamber is to represent the interests of its members in important matters before the state

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[1] Pursuant to this Court's Rule 37.6, *amici* affirm that no counsel for any party has authored this brief in whole or in part, that no such counsel or party made a monetary contribution to fund the preparation or submission of this brief, and that no person other than *amici* and their counsel made such a monetary contribution. Pursuant to this Court's Rule 37.2, counsel of record for both petitioners and respondents were notified of the intent to file this brief at least 10 days prior to the filing of this brief, and both parties gave consent to the filing of *amicus* briefs.

and federal courts, legislatures, and executive branches. To that end, the Chamber files *amicus* briefs in cases that raise issues of vital concern to the nation's business community.

The issue of how loss causation must be pled in securities class actions is one of recurring importance to the publicly traded member companies of the NAM and the Chamber. The element of loss causation serves a central gate-keeping role by requiring securities fraud plaintiffs to plead and prove that any alleged loss resulting from a stock price drop was the result of fraud and not the product of numerous other factors that can impact a company's stock price. Meaningful enforcement of the loss causation requirement at the pleading stage reduces the likelihood that companies will be drawn into costly securities class actions by plaintiffs armed with nothing more than a stock price drop and a fanciful theory manufactured after the fact.

The standard for pleading loss causation takes on particular importance during difficult economic times such as these, where the vast majority of public companies have experienced falling stock prices due to macroeconomic conditions. While common sense would dictate that such losses should not expose issuers to claims of securities fraud, a weak pleading standard for loss causation – the element best suited to weed out such suits – opens the door to precisely such litigation. Thus, the NAM and the Chamber are concerned that the thousands of public companies in their respective constituencies could face expanded

exposure to opportunistic strike suits, "[t]he very pendency of [which] may frustrate or delay normal business activity." *Merrill Lynch, Pierce, Fenner & Smith Inc. v. Dabit*, 547 U.S. 71, 80 (2006).

INTRODUCTION

The Court should grant the petition for writ of certiorari filed by Gilead Sciences, Inc. ("Gilead") and various of its current and former executive officers. The Ninth Circuit has articulated a standard for pleading loss causation which not only empties the requirement of its potency, but conflicts with every other Circuit that has ruled on the issue, and this Court's recent decision in *Bell Atlantic v. Twombly*, 550 U.S. 544 (2007). The Court therefore should grant the petition to resolve the conflict and create a consistent and sensible standard for the pleading of loss causation in securities fraud actions.

REASONS FOR GRANTING THE PETITION

In *Dura Pharmaceuticals v. Broudo,* 544 U.S. 336 (2005), this Court reaffirmed the critical importance of the loss causation requirement in securities fraud cases, ruling that such actions cannot proceed unless the operative complaint demonstrates that alleged losses were caused by defendants' misrepresentations, and not by any of the other "tangle of factors" that can cause a decline in a company's stock price.

Id. The Court also mandated that plaintiffs plead facts that would allow a fact finder to disentangle the impact of the alleged fraud from other market factors such as "changed economic circumstances, changed investor expectations, new industry-specific or firm-specific facts, conditions, or other events, which taken separately or together account for some or all of [a stock's] lower price." *Id.* at 343. The *Dura* opinion emphasized that a failure to vigorously enforce the loss causation requirement would effectively "transform a private securities action into a partial down-side insurance policy." *Id.* at 348.

In this action, respondents allege they were damaged by a drop in Gilead's stock price on October 28, 2003, after an unfavorable earnings release was issued by the company. Respondents' theory, however, of how that stock price drop was the product of fraud was rightfully dismissed by the district court as "too attenuated," and lacking in factual support. Specifically, respondents alleged that Gilead was secretively engaged in impermissible "off label" marketing of the drug Viread, which supposedly resulted in artificially inflated sales of the product. When the Food and Drug Administration ("FDA") sent Gilead a letter on July 29, 2003 warning it against the use of such marketing, respondents allege that doctors reacted by scaling back prescriptions of Viread, causing sales to decrease and leading to a drop in Gilead's stock price three months later.

The district court correctly rejected respondents' speculative theory because it was premised on assertions that were unsupported by well-pled facts. No facts were set forth substantiating that the FDA letter led to a decrease in doctor prescriptions of Viread – to the contrary, analyst reports cited in the complaint actually predicted an *increase* in demand. Nor were respondents able to explain how an announcement made in August of 2003 could cause a stock price drop *three months later*, especially given that the complaint itself alleged that the stock traded in an open and efficient market. Similarly, the complaint provided no basis for the court to make the determination – as required by *Dura* – of what portion of the stock price drop was the result of misconduct, if any, and what was attributable to other intervening market factors.

In reviewing the lower court decision, the Ninth Circuit acknowledged the importance of the loss causation requirement, but nonetheless ruled that because respondents' theory of loss causation was not "per se implausible," the threshold for pleading loss causation had been met. The lack of specific facts supporting respondents' arguments did not deter the Ninth Circuit from breaking with its sister Circuits and overruling the district court's decision, and in so doing establishing a wholly inadequate standard for the pleading of loss causation.

I. THE NINTH CIRCUIT'S RULING WILL RENDER COMPANIES MORE SUSCEPTIBLE TO STRIKE SUITS, ESPECIALLY IN DIFFICULT ECONOMIC CONDITIONS.

The Ninth Circuit has articulated a standard for pleading loss causation that is trivially easy to satisfy – all that is required is a stock price drop and a modicum of imagination. The ruling effectively obviates the gate-keeping function of the loss causation requirement, and will have particularly pernicious effects on American businesses in a down economy where significant declines in company stock prices are commonplace. Indeed, the facts of the *Gilead* case serve as a template by which an opportunistic shareholder can skirt the loss causation requirement in securities class actions.

Under the Ninth Circuit standard, loss causation can be pled by simply pointing to: 1) an unfavorable earnings release followed by a drop in the company's stock price – an occurrence which, in today's market conditions, is a common if not ubiquitous event; and 2) a "not per se implausible" theory connecting the unfavorable earnings to negative news about the company in the past.

A plaintiff is *not* required, however, to provide specific facts supporting a purported theory of how a stock price drop was caused by fraud, notwithstanding Rule 9(b)'s requirement to plead the elements of fraud with particularity. In this case, the Ninth Circuit allowed respondents to simply state various

conclusions without offering any corroborating details, *e.g.*, that the FDA letter caused doctors to cut back on Viread prescriptions, without pleading a shred of supporting facts. Freeing plaintiffs of any obligation to provide factual substantiation of their loss causation theory threatens an increase in a practice that Congress has decried, *i.e.*, the "filing of lawsuits against issuers of securities and others whenever there is a significant change in an issuer's stock price, without regard to any underlying culpability of the issuer." H.R. Conf. Rep. No. 104-369, at 28 (1995).

Nor need a plaintiff show any temporal proximity between the revelation of the alleged fraud and the stock price drop that it purportedly caused. In this instance, the Ninth Circuit paid no heed to the fact that it took three months before the market allegedly reacted to a disclosure that Gilead was engaged in fraudulent marketing activity, and downplayed the inherent implausibility of such a sluggish reaction in an efficient market. It thus becomes unclear what, if any, limits there are to the ability of a plaintiff to reach backwards in time for a *post hoc* explanation of how a stock price drop was caused by "fraud," vastly expanding the universe of speculative theories that can be generated to satisfy the loss causation requirement.

In the same vein, it is not necessary under the Ninth Circuit standard to demonstrate how alleged losses from a stock price drop were caused by fraud and not any other market factor. The October 28

earnings announcement that preceded the stock drop at issue disclosed a variety of issues that contributed to Gilead's disappointing earnings. Notably, off-label marketing was not mentioned. Each of the factors which were discussed, however, arguably contributed to the fall in the company's stock price at issue. Contrary to the dictates of *Dura*, neither the respondents nor the Ninth Circuit made any effort to explain why the stock price drop could not have been the result of these or other non-fraudulent events. This omission takes on particular importance in a down stock market, where a host of macroeconomic and other factors contribute to falling prices, all of which can be ignored by a plaintiff under the Ninth Circuit's analysis of loss causation.

Equally troubling is the Ninth's Circuit's attempt to downplay the speculative nature of respondents' loss causation theory by asserting that its validity can be tested through the discovery process. This is precisely what *Dura* sought to avoid in requiring that the loss causation requirement be strictly enforced, noting it guards against "'the routine filing of lawsuits . . . with only a faint hope that the discovery process might lead eventually to some plausible cause of action.'" *Dura*, 544 U.S. at 347 (citation omitted); *see also Tellabs v. Makor*, 551 U.S. 308 (2007) ("[p]rivate securities fraud actions . . . if not adequately contained, can be employed abusively to impose substantial costs on companies and individuals whose conduct conforms to the law"). Indeed, the threat of costly discovery abuse was a significant

motivating factor in Congress's enactment of the Private Securities Litigation Reform Act of 1995, which stayed all discovery in securities fraud actions until a plaintiff's complaint survived a motion to dismiss. 15 U.S.C. § 77z-1(b)(1); § 78u-4(b)(3)(B). Allowing courts to apply only minimal scrutiny to the loss causation requirement until completion of discovery would undermine this critical safeguard.

Moreover, while it is true that loss causation theories based on idle speculation can be ultimately disproven as the evidentiary record emerges, that fact is of scant comfort to companies that inevitably will be sued. As this Court has recognized, "[e]ven weak cases brought under [the securities laws] may have substantial settlement value . . . because '[t]he very pendency of the lawsuit may frustrate or delay normal business activity.'" *Merrill Lynch,* 547 U.S. at 80 (2006), *citing Blue Chip Stamps v. Manor Drug Stores*, 421 U.S. 723, 740 (1975). Indeed, the fundamental premise of *Dura* was that enforcement of the loss causation requirement *at the pleading stage* serves a vital role in ensuring that "largely groundless claim[s]" are not allowed to proceed. *Dura*, 544 U.S. at 347.

In sum, the Ninth Circuit's ruling threatens the vitality of the critical loss causation principles articulated in *Dura*, and re-opens the door to abuses that Congress has specifically attempted to eliminate. The Court should grant the Petition in order to correct this misguided standard.

II. THE NINTH CIRCUIT'S RULING CREATES A SPLIT BETWEEN THE CIRCUITS ON THE CRITICAL ISSUE OF LOSS CAUSATION AND IS INCONSISTENT WITH THIS COURT'S DECISION IN *TWOMBLY*.

A. The Ninth Circuit's Ruling Directly Conflicts With Other Circuits That Require Loss Causation To Be Pled With Factual Specificity.

As detailed in the Petition, each of the five other Circuits that have ruled on how loss causation must be pled have concluded that the particularity requirements of Rule 9(b) apply, or at a minimum demand some amount of factual specificity to be pled in support of a loss causation theory. *See e.g., Tricontinental Indus., Ltd. v. PricewaterhouseCoopers, LLP*, 475 F.3d 824, 842-43 (7th Cir. 2007); *Catogas v. Cyberonics, Inc.*, 292 F. App'x 311, 312-14 (5th Cir. 2008) (per curiam); *Lattanzio v. Deloitte & Touche LLP*, 476 F.3d 147, 158 (2d Cir. 2007); *Teachers' Ret. Sys. v. Hunter*, 477 F.3d 162, 186 (4th Cir. 2007); *Schaaf v. Residential Funding Corp.*, 517 F.3d 544, 549 (8th Cir.) (quotation omitted), *cert. denied*, 129 S. Ct. 222 (2008).

The Ninth Circuit stands alone in its interpretation of the loss causation pleading requirement. This conflict between the Circuits not only raises the threat of inconsistent rulings, it also creates significant motivation for forum shopping. Over the course of the last decade the Ninth Circuit has consistently ranked as either the first or second most active

Circuit in the country for securities class action filings. *See, e.g.*, Cornerstone Research, *Securities Class Action Filings, 2008: A Year in Review* (2009) at 21, available at http://www.cornerstone.com/pdf/practice_securities/2008Filings_Report.pdf. Now that this historical hotbed of securities litigation activity has adopted the nation's most permissive standard for loss causation pleading, plaintiffs will have incentive to seek litigation of their actions in that forum, and the number of cases that will be wrongfully decided under the Ninth Circuit standard (and in conflict with other Circuits) will increase. Companies with nationwide operations will be especially vulnerable – particularly given that the federal securities laws allow for nationwide service of process. The Court should act to resolve this conflict and avoid the economic disruption that inevitably will be caused by the lack of consistency in the loss causation pleading requirement.

B. The Ninth Circuit's Ruling Misapplied The *Twombly* Standard Of Pleading.

The Ninth Circuit's analysis of pleading standards rests heavily on this Court's decision in *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007), a widely-cited opinion that clarified what must be pled for a complaint to pass muster under Rule 8(a). The Ninth Circuit misapplied *Twombly*, however, which when read properly actually rebuts the assertion that respondents had pled sufficient facts to support their loss causation claims.

As an initial matter, *Twombly* expressly noted that the pleading standards it articulated were only applicable to actions applying Rule 8(a), and did not address the requirements of Rule 9(b) or any other "'heightened' pleading standard." *Twombly*, 550 U.S. at 570, n.14. Thus, reliance on *Twombly* is appropriate only if it is determined that Rule 8(a) is the applicable pleading standard. No such determination was made here, and indeed, the Ninth Circuit expressly chose *not* to rule on whether Rule 8(a) or Rule 9(b) applied to the pleading of loss causation. Thus, to the extent that one concludes, as the Fifth and Seventh Circuits have, that Rule 9(b) governs, the entirety of the Ninth Circuit's *Twombly*-based analysis is rendered inapposite.

Moreover, even if one does assume that Rule 8(a) governs pleading of loss causation, the Ninth Circuit's holding is still inconsistent with *Twombly*, which requires the pleading of sufficient "facts to state a claim to relief that is *plausible on its face*." *Twombly*, 550 U.S. at 570 (emphasis added). The Ninth Circuit's formulation – that a loss causation theory cannot be "per se implausible" – bears superficial resemblance to *Twombly*, but is in fact an impermissible relaxing of the governing standard. A "per se implausible" requirement by definition does not exclude "moderately implausible" or even "highly implausible" loss causation theories, neither of which is acceptable under *Twombly*, which requires pleading of theories that are *plausible*. *Id.*

Put another way, the Ninth Circuit's "per se implausible" test is the functional equivalent of the oft-cited pleading standard articulated in *Conley v. Gibson*, 355 U.S. 41, 45-46 (1957), which only permitted dismissal if it was "beyond doubt that the plaintiff can prove no set of facts in support of his claim." *Twombly*, however, notably disavowed the *Conley* standard, because it would allow "a wholly conclusory statement of claim [to] survive a motion to dismiss whenever the pleadings left open the possibility that a plaintiff might later establish some 'set of [undisclosed] facts' to support recovery." *Twombly*, 550 U.S. at 560. The same holds true for the Ninth Circuit's standard of loss causation pleading, which should be similarly discarded and brought in line with the rulings of the other Circuits.

CONCLUSION

For the foregoing reasons, and for the reasons set forth in the petition for writ of certiorari, the petition should be granted.

Respectfully submitted,

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In The

Supreme Court of the United States

GILEAD SCIENCES, INC., *et al.*,

Petitioners,

v.

TRENT ST. CLARE, *et al.*,

Respondents.

On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Ninth Circuit

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INTEREST OF THE *AMICUS CURIAE*[1]

Technology Network ("TechNet") is a network of Chief Executive Officers and senior partners of more than 150 companies in the information technology, biotechnology, venture capital, investment banking and legal industries. The association is organized to promote the growth of the technology industry and to advance America's global leadership in innovation by building long-term relationships among technology leaders and policy makers. The majority of TechNet's members lead companies capitalized through publicly traded shares on the Nation's major stock exchanges. TechNet's members represent the leading edge of developing, manufacturing, and marketing emerging technologies.

This case presents the question of the proper standard for pleading "loss causation" in securities fraud cases. The issue is one of recurring importance

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[1] Pursuant to this Court's Rule 37.6, counsel for *amicus* represent that they authored this brief in its entirety and that none of the parties or their counsel, nor any other person or entity other than *amicus*, its members, or counsel, made a monetary contribution intended to fund the preparation or submission of this brief. Sup. Ct. R. 37.6. Further, pursuant to this Court's Rules 37.3(a) and 37.2, TechNet received permission to file this brief from both parties to this matter, and respondent was timely notified of the intent to file this brief. A copy of each party's notice of consent is on file with the Clerk of the Court.

for members and investors in the emerging technology industries. Companies in these industries rely heavily on public capital investments to develop new ideas, many of which may never become viable in the marketplace. These companies' stock prices are often highly volatile, as the market potential of their technologies waxes and wanes.

Due to the volatility of their stock, technology companies are frequent targets of private securities litigation, and such litigation is therefore of special concern. Congress recognized this concern when it enacted the Private Securities Litigation Reform Act of 1995 ("PSLRA"), Pub. L. No. 104-67, 109 Stat. 737 (1995), to combat the high cost of frivolous securities litigation. 141 CONG. REC. H2760 (daily ed. Mar. 7, 1995) (statement of Rep. Cox) ("[h]igh-tech and biotech companies have paid 40 percent of the costs of strike suit settlements"). This concern persists even after enactment of the PSLRA: "every year since the 1995 enactment of the PSLRA, the high-tech sector has been in the unenviable position of being the most frequently sued industry group." *See* PRICEWATERHOUSECOOPERS, 2006 SECURITIES LITIGATION STUDY, at 14 (Grace Lamont & Patricia Etzold eds., 2007) *available at* http://10b5.pwc.com.

INTRODUCTION

The Ninth Circuit ruled in this case that plaintiffs need only articulate a theory of loss causation

that is not "per se implausible." This ruling improperly restricts the ability of district courts to serve as gatekeepers and dismiss unmeritorious suits in which plaintiffs do not plead the facts showing a causal link between an alleged fraud and a decline in the price of a stock. As a result, the ruling abrogates the protections of the PSLRA and subjects technology and other companies whose stock prices are inherently volatile to the burden and expense of unmeritorious litigation.

REASONS FOR GRANTING THE PETITION

I. UNMERITORIOUS SECURITIES LITIGATION IMPOSES SIGNIFICANT COSTS ON TECHNOLOGY COMPANIES AND SOCIETY

A. Technology Companies Are A Favored Target For Securities Class Action Strike Suits

The technology industry gets more than its share of securities litigation. "[T]he high technology sector [is] consistently a favorite target of plaintiffs' lawyers." Marilyn F. Johnson, Karen K. Nelson & A.C. Pritchard, *Do the Merits Matter More? The Impact of the Private Securities Litigation Reform Act*, 23 J.L. ECON. & ORG. 627, 629 (2006). In particular, "the high-technology sector has been the most common target for class actions both before and after the PSLRA, unlike other sectors where the incidence of litigation has fluctuated over time for

reasons unrelated to passage of the PSLRA." *Id.* at 636. "[E]very year since the 1995 enactment of the PSLRA, the high-tech sector has been in the unenviable position of being the most frequently sued industry group." PRICEWATERHOUSECOOPERS, 2006 SECURITIES LITIGATION, at 14; *accord* PRICEWATERHOUSECOOPERS, 2007 SECURITIES LITIGATION STUDY, at 15 (Grace Lamont & Patricia Etzold eds., 2008) *available at* http://10b5.pwc.com ("[T]echnology companies remained the industry most frequently involved in private securities class actions.").[2] Audit Integrity reported in 2006 "[c]ertain industries are inherently more risky than others" and that "litigation risk differs across industries," with technology firms facing the highest probability of litigation. Ophir Gottlieb, *Audit Integrity News: Services Industry Litigation Risk* (Sept. 18, 2006) (on file with author).[3]

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[2] Filings against financial sector companies resulting from the recent credit crisis have now exceeded those against technology companies. *See* Stephanie Plancich and Svetlana Starykh, *2008 Trends in Securities Class Actions*, NERA ECON. CONSULTING, at 5 (Dec. 2008).

[3] Audit Integrity also found that the technology industry faces the greatest risk of litigation with an 11.63% probability of litigation over a two-year horizon. Audit Integrity, *The Audit Integrity Multi-Factor Litigation Model: A Leading Indicator of Class Action Lawsuits*, at 9 (Mar. 15, 2006) (on file with author). The average publicly traded company, on the other hand, "faces a 7.9% probability that it face at least one shareholder class action lawsuit over a five-year period." Todd Foster, Ronald I. Miller & Stephanie Plancich, *Recent Trends in Shareholder Class Action Litigation: Filings Plummet, Settlements Soar*,

(Continued on following page)

Technology companies are the frequent targets of securities class actions because of their inherently volatile stock prices. Many securities class actions are triggered not by any actual fraud but by nothing more than a drop in the company's stock price. *See* Audit Integrity, *The Audit Integrity Multi-Factor Litigation Model*, *supra*, at 9 ("[l]arge declines in stock price can be the catalyst for class action lawsuits"). In fact, "litigation probabilities for companies suffering a severe stock loss (defined as [a less than twenty-five percent] price drop in one year) are approximately two to three times as high as probabilities for companies whose prices were more stable." *Id.* The volatility of technology companies' stock prices leads to more stock price declines. In a study focusing on the financial, industrial, consumer, health, and technology sectors, the authors found that "[t]he technology sector has the largest standard deviation among all five sectors, which is consistent with the general impression that technology stocks are more volatile relative to other sectors." Farooq Malik & Syed Aun Hassan, *Modeling Volatility in Sector Index Returns with GARCH Models Using an Iterated Algorithm*, 28 J. ECON. & FIN. 211, 215 (Summer 2004). Furthermore, according to Jason Hall, the "high volatility Technology" sector is "characterised by high growth, a high level of innovation and significant probability of failure." *See* Jason Hall, *The Impact of*

NERA ECON. CONSULTING, at 3 (Jan. 2007) *available at* http://www.nera.com/PracticeArea.asp?PA_ID=44&more=Publications.

Growth, Volatility and Competitive Advantage on Equity, at 1 (U. of Queensland Bus. Sch. Working Paper, Jan. 18, 2007) *available at* http://ssrn.com/abstract=957945. In fact, "[t]he factor that seems to explain unusual volatility best is technology." G. William Schwert, *Stock Volatility in the New Millennium: How Wacky is Nasdaq?*, 49 J. OF MONETARY ECON. 3, 3 (Jan. 2002).

B. Securities Class Action Litigation Imposes Significant Costs On Technology Companies Without Regard To The Merits

Even unmeritorious securities class actions impose a heavy tax on technology companies.[4] Approximately eighty percent of the cost of securities litigation is incurred in discovery, without regard to the merits of the litigation. *See* Michael A. Perino, *Did the Private Securities Litigation Reform Act Work?*, 2003 U. ILL. L. REV. 913, 921 n.36 (2003)

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[4] That tax is borne largely by the company's shareholders: "because the costs of securities class actions – both the settlement payments and the litigation expenses of both sides – fall largely on the defendant corporation, its shareholders ultimately bear these costs indirectly and often inequitably." *See* John C. Coffee, Jr., *Reforming the Securities Class Action: An Essay on Deterrence and its Implementation*, 106 COLUM. L. REV. 1534, 1536 (Nov. 2006). Indeed, in enacting the PSLRA, Congress expressed specific concern that "innocent parties are often forced to pay exorbitant 'settlements'," which resulted in the company's "own investors" being the "ultimate losers." H.R. CONF. REP. NO. 104-369, at 32 (1995).

(citing H.R. CONF. REP. No. 104-369, at 37 (1995)). Over a decade ago, such discovery costs approached, and held the potential to exceed, two million dollars. *See* Joseph A. Grundfest, *Why Disimply,* 108 HARV. L. REV. 727, 742 (1994-95). With the more recent advent of electronic discovery, those costs have likely soared even higher. *See* John Montaña, *Strategies for Minimizing Litigation Risks, Costs*, INFO. MGMT. J. 10 (Jan. 1, 2008) *available at* 2008 WLNR 5994603 (noting that the "total number of e-mails being analyzed in a single lawsuit commonly reaches 3 million or more").

To the costs of discovery must be added the costs of settlement. These can be significant. "The median settlement amount reached a high of $9 million in 2007, surpassing all prior median amounts for cases settled in a given year. This is partly because the percentage of cases settling for $10-20 million increased substantially from prior years." Laura E. Simmons & Ellen M. Ryan, *Securities Class Action Settlements: 2007 Review and Analysis*, CORNERSTONE RESEARCH, at 2 (2008).

Despite the cost, companies often settle not because of wrongdoing, but because of basic rational economics – the cost of settlement may be less expensive than the costs of protracted discovery and litigation. *See* John Bohn & Stephen Choi, *Fraud in the New-Issues Market: Empirical Evidence on Securities Class Actions*, 144 U. PENN. L. REV. 903, 918-19 (1995-96). Professor Grundfest has suggested that such settlements for amounts less than the cost of

taking the matters to trial signal that the claims lacked merit. *See* Grundfest, *supra*, at 742-43.

Abusive securities litigation imposes substantial indirect costs as well. It diverts management resources to litigation and away from vital innovations in biotech, medicine, communications, and information technology. It raises the cost of capital for technology and other companies, impairing their ability to compete in global markets. By discouraging innovation, securities class action strike suits thus burden our economy and our society as a whole, especially the elderly, infirm, and others whose health and quality of life may depend on advances in these areas.

II. THE PSLRA'S PROTECTIONS AGAINST ABUSIVE SECURITIES LITIGATION SHOULD NOT BE DILUTED AT THE PLEADING STAGE

The PSLRA was enacted to protect technology and other companies against these abuses and to curb frivolous securities lawsuits which result in "targeting of deep-pocket defendants, vexatious discovery requests and manipulation by class-action lawyers." *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 127 S. Ct. 2499, 2508 (2007) (citations omitted); *see also* H.R. CONF. REP. No. 104-369, at 31 (1995) (PSLRA prompted by significant evidence of "abusive and meritless suits," including evidence of "routine filing of lawsuits against issuers of securities . . . whenever there is a significant change in an issuer's stock price, without regard to any underlying culpability of the issuer").

The securities laws are intended not to "provide investors with broad insurance against market losses, but to protect them against those economic losses that misrepresentations actually cause." *Dura Pharmaceuticals, Inc. v. Broudo*, 544 U.S. 336, 345 (2005). To this end, the PSLRA expressly imposes on plaintiffs the burden of pleading and proving loss causation and "makes clear Congress' intent to permit private securities fraud actions for recovery where, but only where, plaintiffs adequately allege and prove the traditional elements of causation and loss." *Id.* at 345-46. In addition, the PSLRA protects companies against the costs associated with discovery in abusive securities litigation by imposing a stay on all discovery until after the court has determined that plaintiffs have pleaded a complaint sufficiently to withstand a motion to dismiss. 15 U.S.C. § 78u-4(b)(3)(B) (2008).

As suggested by the stay of discovery until after the court has ruled on a motion to dismiss, Congress intended the pleading stage to provide a meaningful opportunity to end costly strike suits. Therefore, the safeguards Congress adopted in the PSLRA must not be diluted at the pleading stage. As this Court recognized in *Dura*, allowing a plaintiff to get past the pleading stage without giving any indication of economic loss and proximate cause would permit a plaintiff "with a largely groundless claim to simply take up the time of a number of other people, with the right to do so representing an *in terrorem* increment of the settlement value, rather than a reasonably founded hope that the [discovery] process will reveal

relevant evidence." *Dura Pharms., Inc.*, 544 U.S. at 347 (*citing Blue Chip Stamps v. Manor Drug Stores*, 421 U.S. 723, 741 (1975)). The district courts must be permitted to dismiss abusive securities class actions in which plaintiffs do not allege the facts linking a decline in the company's stock price to an alleged fraud.

III. THE NINTH CIRCUIT'S STANDARD IMPROPERLY ELIMINATES PLAINTIFFS' BURDEN TO PLEAD FACTS SUFFICIENT TO SUPPORT THEIR THEORY OF LOSS CAUSATION

Plaintiffs in *Dura* made no attempt to plead loss causation. *Dura Pharms., Inc.*, 544 U.S. at 346-47 (complaint provided no notice of relevant economic loss or causal connection to alleged misrepresentation). This Court found that the complaint there did not meet even the lesser standard of Rule 8(a)(2) of the Federal Rules of Civil Procedure (requiring a short and plain statement of the claim showing that the pleader is entitled to relief). *Id.* at 346. The Court was not required by the facts of that case to decide whether the Federal Rules or the securities statutes impose any special further requirement for pleading loss causation. *Id.* This case presents that question and demonstrates that if private securities actions are not to be transformed into partial downside insurance policies, then plaintiffs must be required to plead facts to support their theories of loss causation.

A. The Ninth Circuit's Standard Abrogates The Loss Causation Requirement At The Pleading Stage

Plaintiffs alleged in this case that the stock price drop on the company's October 28, 2003 announcement of disappointing earnings was actually caused by the company's August 8, 2003 public revelation of a letter in which the FDA warned the company against off-label marketing of its products. *In re Gilead Sciences Sec. Litig.*, Fed. Sec. L. Rep. (CCH) P93,891 (N.D. Cal. May 12, 2006) *available at* 2006 WL 1320466, at *2, *9 (N.D. Cal. 2006). Although the disappointing earnings announcement made no reference to the FDA letter or off-label marketing, plaintiffs' theory was that the FDA warning letter could have reduced demand for the company's product, leading to lower earnings. *Gilead*, 2006 WL 1320466, at *7, Fed. Sec. L. Rep. (CCH) P93,891 at 90,619.

The problem with plaintiffs' theory was that nothing in the subsequent press releases linked any misstatements, omissions, or fraud about Gilead's alleged off-label marketing to lowered demand for the company's product. Plaintiffs alleged that analyst reports linked the FDA warning letter to lowered demand, but in fact none of the analyst reports plaintiffs presented drew this connection. *See Gilead*, 2006 WL 1320466, at *7, Fed. Sec. L. Rep. (CCH) P93,891 at 90,619 ("[t]he reports do not predict a decrease in demand at all"). The district court accordingly dismissed the complaint for failure

to plead loss causation under *Dura*. *Gilead*, 2006 WL 1320466, at *10, Fed. Sec. L. Rep. (CCH) P93,891 at 90,620.

The Ninth Circuit reversed and ruled that plaintiffs adequately plead loss causation so long as they plead a theory that is not "facially implausible." *In re Gilead Sciences Sec. Litig.*, 536 F.3d 1049, 1057 (9th Cir. 2008). The Ninth Circuit dismissed the district court's concerns about the discrepancy between plaintiffs' allegations and the analyst reports and held that the complaint met the standard of Rule 9 as well as that of Rule 8. *Id.* at 1056.[5]

In so holding, the Ninth Circuit has effectively abrogated plaintiffs' burden to plead loss causation. So long as plaintiffs can construct a theory of loss causation plausible on its face, it does not matter whether that theory is consistent with or supported by the publicly-available facts, such as analyst reports or other public disclosures. Even plaintiffs in *Dura* could have passed this test by alleging that the market understood the company's earlier announcement of disappointing earnings to have resulted from

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[5] As an essential (and statutory) element of a claim for securities fraud, loss causation is one of the "circumstances constituting fraud" to which Rule 9(b) of the Federal Rules of Civil Procedure applies. This point is discussed at length in the Brief for the Biotechnology Industry Organization, The Bay Area Bioscience Association, and Biocom as *Amici Curiae* Supporting Petitioners and will not be repeated here. As discussed below, plaintiffs' allegations do not in any event satisfy even the lower requirements of Rule 8, much less those of Rule 9(b).

the then-undisclosed problems with approval of the company's asthmatic spray device. *See, e.g.*, *Dura Pharms., Inc.*, 544 U.S. at 338-39 (alleged fraud disclosed eight months after market reaction to disappointing earnings).

B. The Ninth Circuit's Standard Conflicts With The Standards Of Other Circuits

Other circuits to address the issue have not so lightly dispensed with the requirement that plaintiffs plead the facts in support of their theory of loss causation. Most disagree with the Ninth Circuit and have imposed heightened pleading requirements – some more rigorous than others.

In *Lentell v. Merrill Lynch & Co.*, the Second Circuit affirmed dismissal of the complaint alleging that defendant's misrepresentations and omissions induced a "purchase-time value disparity" between the price paid for a security and its "true investment quality." 396 F.3d 161, 167, 174 (2d Cir. 2005). The court held that plaintiff must plead not only that loss occurred following an announcement, but also that "the misstatement or omission concealed something from the market that, when disclosed, negatively affected the value of the security." *Id.* at 173-74.

In *Teachers' Ret. Sys. Of La. v. Hunter*, the Fourth Circuit required that loss causation be pled with "sufficient specificity to enable the court to evaluate whether the necessary causal link exists." 477 F.3d 162, 186 (4th Cir. 2007). The court specifically

required that plaintiffs allege that the market reacted to the disclosure of new facts that caused the defendants' prior representations to have been fraudulent. *Id.* at 186-87.

The Fifth Circuit's reading of *Dura* required plaintiffs to "allege . . . that the market reacted negatively to a corrective disclosure, which revealed the falsity of [the defendant's] previous representations." *Catogas v. Cyberonics, Inc.*, 292 F. App'x 311, 314 (5th Cir. 2008). In *Catogas,* the Fifth Circuit rejected the theory of loss causation proposed by plaintiffs as too tenuous because the only information not previously disclosed to the market did not reveal the alleged fraud. *Id.* at 315-16.

The Seventh Circuit addressed the issue in *Tricontinental Indus., Ltd. v. PricewaterhouseCoopers, LLP*, 475 F.3d 824 (7th Cir. 2007). The court similarly interpreted *Dura* to require that the complaint allege that a material misrepresentation caused plaintiff to suffer a loss when that material misrepresentation became generally known and "not simply that the misrepresentation 'touches upon a later economic loss.'" 475 F.3d at 843 (citing *Dura*, 544 U.S. at 343).

The Eighth Circuit ruled consistently, citing both *Dura* and *Bell Atl. Corp. v. Twombly*, 127 S. Ct. 1955 (2007), that plaintiffs must allege "sufficient factual information to provide the 'grounds' on which the claim rests" and that the "'loss [was] caused by the materialization of the concealed risk.'" *Schaaf v.*

Residential Funding Corp., 517 F.3d 544, 549-50 (8th Cir. 2008) (*quoting Lentell*, 396 F.3d at 173).

C. The Ninth Circuit Should Have Required Plaintiffs To Allege The Facts To Support Their Theory Of Loss Causation

Rule 8 of the Federal Rules of Civil Procedure requires more than plaintiffs alleged here. Rule 8 requires plaintiffs to plead "enough *facts* to state a claim to relief that is plausible on its face." *Twombly*, 127 S. Ct. at 1974 (emphasis added).[6] Where, as here, plaintiffs do not plead the facts in support of their theory of loss causation, "'this basic deficiency should . . . be exposed at the point of minimum expenditure of time and money by the parties and the court.'" *Id.* at 1966 (*citing* 5 CHARLES ALAN WRIGHT & ARTHUR R. MILLER, FEDERAL PRACTICE AND PROCEDURE, § 1216, at 233-34 (3d ed. 2004)).

Had the Ninth Circuit followed *Twombly* and the decisions of the other circuits discussed above, it would have affirmed the district court's dismissal of the complaint. It was not enough for plaintiffs to allege a conclusion that the company's lowered

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[6] Although *Twombly* arose in the context of an antitrust claim, its standard has been applied to securities fraud complaints. *See, e.g.*, *ATSI Commc'ns, Inc. v. Shaar Fund, Ltd.*, 493 F.3d 87, 98 n.2 (2d Cir. 2007) (affirming the district court's dismissal and finding insufficient facts alleged regarding loss causation).

earnings resulted from the FDA warning letter where, as here, the analyst reports and other public disclosures did not make that connection. The complaint here offers only legal theories and conclusions; it does not allege the facts showing that loss resulted when a material misrepresentation was revealed or became generally known.

Under the Ninth Circuit's standard, plaintiffs will be permitted to pursue groundless securities fraud claims in the hopes that discovery might turn up facts to support their theory of loss causation and if it does not, that they might still be able to use the threatened costs of discovery to wrest a settlement from defendants. If plaintiffs are not required to plead the facts sufficient "to raise a right to relief above a speculative level," *Twombly*, 127 S. Ct. at 1964, such groundless claims will be limited only by the creativity of the plaintiffs' bar.

Any price drop can be conclusorily alleged to have been caused by some undisclosed fact, and the Ninth Circuit's ruling would therefore "tend to transform a private securities action into a partial downside insurance policy." *Dura Pharms., Inc.*, 544 U.S. at 347-48. By allowing plaintiffs to plead theories and conclusions unsupported by the facts, the Ninth Circuit effectively waives the requirement of loss causation at the pleading stage and eliminates important protections against abusive securities litigation intended by the PSLRA. The Ninth Circuit's ruling conflicts with the intent of the PSLRA, with the decisions of other circuits and with the principles

articulated by this Court in *Dura* and *Twombly*. It should be reversed.

CONCLUSION

For the foregoing reasons, the petition for a writ of certiorari should be granted.

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GILEAD SCIENCES, INC., *et al.*,
Petitioners,

v.

TRENT ST. CLARE, *et al.*,
Respondents.

On Petition for a Writ of Certiorari To the United States Court of Appeals For the Ninth Circuit

BRIEF OF WASHINGTON LEGAL FOUNDATION AS *AMICUS CURIAE* IN SUPPORT OF PETITIONERS

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QUESTION PRESENTED

Whether a plaintiff in a "fraud on the market" case under Section 10(b) of the Securities Exchange Act must plead facts with sufficient particularity to support a reasonable, non-speculative belief that the plaintiff can ultimately prove loss causation.

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BRIEF OF WASHINGTON LEGAL FOUNDATION AS AMICUS CURIAE IN SUPPORT OF PETITIONERS

INTERESTS OF *AMICUS CURIAE*

The Washington Legal Foundation (WLF) is a non-profit public interest law and policy center with supporters in all 50 States.[1] WLF devotes a substantial portion of its resources to defending free-enterprise, individual rights, and a limited and accountable government.

To that end, WLF has appeared before this and other federal courts in numerous cases raising issues relating to the proper scope of the federal securities laws. *See, e.g., Stoneridge Inv. Partners, LLC v. Scientific Atlanta, Inc.*, 128 S. Ct. 761 (2008); *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 127 S. Ct. 2499 (2007); *Merrill Lynch, Pierce, Fenner & Smith, Inc. v. Dabit*, 547 U.S. 71 (2006); *Dura Pharmaceuticals, Inc. v. Broudo*, 544 U.S. 336 (2005).

WLF also has participated extensively in litigation in support of its view that off-label use of FDA-approved products by licensed physicians is an important component of optimal health care and ought not to be restricted unnecessarily. WLF successfully challenged the constitutionality of certain FDA

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[1] Pursuant to Supreme Court Rule 37.6, WLF states that no counsel for a party authored this brief in whole or in part; and that no person or entity, other than WLF and its counsel, made a monetary contribution intended to fund the preparation and submission of this brief. More than ten days prior to the due date, counsel for WLF provided counsel for Respondents with notice of its intent to file this brief.

restrictions on speech about off-label uses and has in place a permanent injunction against enforcement of those restrictions. *Washington Legal Found. v. Friedman*, 13 F. Supp. 2d 51 (D.D.C. 1998), *appeal dism'd*, 202 F.3d 331 (D.C. Cir. 2000).

WLF is concerned that the Ninth Circuit's decision essentially eliminates the "loss causation" requirement as a check on frivolous securities litigation alleging stock fraud. If Respondents' complaint is deemed sufficient to withstand a motion to dismiss despite failing to supply any facts that would render plausible their claim that their losses were caused by Petitioners' alleged material misrepresentations, few if any securities fraud complaints would be subject to dismissal at the pleadings stage. WLF does not believe that the Ninth Circuit's overly lenient pleadings standard is faithful to Congress's intent when it adopted the Private Securities Litigation Reform Act of 1995 (PSLRA), Pub. L. No. 104-67, 109 Stat. 737.

WLF is filing this brief because of its interest in the fair adjudication of lawsuits raising securities law issues; it has no interest, financial or other, in the outcome of this lawsuit. Because of its lack of direct economic interests, WLF believes that it can assist the Court by providing a perspective that is distinct from that of any party. WLF is filing its brief with the consent of all parties; letters of consent have been lodged with the Court.

STATEMENT OF THE CASE

This case raises important issues regarding the

circumstances under which a complaint alleging securities fraud is subject to dismissal under Fed.R.Civ.P. 12(b)(6) for failure to adequately allege "loss causation." The Ninth Circuit held that a plaintiff adequately alleges loss causation so long as he alleges facts to support a not "facially implausible" theory regarding how the defendant's alleged misrepresentation caused the plaintiff's loss. Pet. App. 17a. If the not-facially-implausible standard is met, then "the court's skepticism is best reserved for later stages of the proceedings." *Id.*

Respondents are several individuals who allege that they suffered losses after purchasing shares of Petitioner Gilead Sciences, Inc. in reliance on material misrepresentations regarding Gilead's financial condition. If Respondents really did lose money from their investment in Gilead, they are among a very small handful of investors who suffered that fate. The performance of Gilead common stock has been nothing short of spectacular during the past decade. Attached as Appendix A is a chart showing the price of Gilead common stock from January 1, 2002 to March 13, 2009. During that period, the stock has appreciated in value more than 400% – even taking into account the sharp decline experienced by almost all equities since September 2008. While, as is true of all publicly traded stock, Gilead has had some up-and-down fluctuations, Gilead's downward fluctuations have been far less pronounced than those for most other stocks. Indeed, as the chart demonstrates, the October 29, 2003 downward fluctuation that is the subject of this lawsuit was extremely short-lived; the stock regained all of its lost value by December 2, less than five weeks later. The

chart also demonstrates Gilead's consistent stock appreciation; the value of Gilead common stock was greater on December 31 of every year during this decade than it was on the preceding December 31. Investors who purchased Gilead stock during the class period applicable to this lawsuit (July 14 to October 28, 2003) and who held on to their stock would have more than tripled their investments.

Petitioner Gilead is a biopharmaceutical company that discovers, develops, and commercializes therapeutics for the care of patients with life-threatening diseases.[2] Viread, an anti-retroviral drug used to treat HIV/AIDS, has been Gilead's best-selling product since its introduction in 2001. Respondents allege that in 2001-2003 Gilead engaged in a campaign to promote Viread for HIV/AIDS treatments for which the federal Food and Drug Administration (FDA) had not approved the drug. They allege that Gilead materially misrepresented the company's financial condition by failing to disclose this allegedly illegal marketing campaign; they allege that the value of Gilead stock was inflated by this omission, which led to overestimations of future sales of Viread.

On August 7, 2003, FDA released a Warning Letter that it had sent to Gilead the previous month; the letter stated that FDA considered certain oral representations made by a Gilead representative at a promotional booth in April 2003 to be improper. The market did not react negatively to the Warning Letter,

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[2] Other Petitioners were officers of Gilead in 2003. All Petitioners are referred to herein collectively as "Gilead."

but Respondents allege that individual doctors did react negatively. They allegedly reacted by writing fewer Viread prescriptions than they would have written but for the Warning Letter.

On October 28, 2003, Gilead announced its financial results for the third quarter of 2003. Those results included a significant drop in reported Viread sales during the third quarter. The next day, Viread common stock dropped 12% in value. Respondents allege that the drop was caused by the disclosure (on August 7) that FDA had issued a Warning Letter alleging that Gilead had been engaged in i mproper promotion of Viread. According to Respondents, the chain of causation worked as follows: (1) disclosure of the Warning Letter caused physicians to be more reluctant to prescribe Viread than they otherwise would have been; (2) although that reluctance led to reduced Viread sales, the market was generally unaware at first of the Warning Letter's impact on sales; (3) on October 28, the market finally became aware that the Warning Letter was having a huge impact on sales – indeed, according to Respondents, much of the announced sales decrease was attributable to physicians' reluctance to write Viread prescriptions after learning of the Warning Letter; and (4) once investors fully understood the significant impact the Warning Letter was likely to have on future sales of Viread, Gilead stock dropped on October 29, 2003.

There are a number of uncontested facts that throw into considerable doubt Respondent's explanation for the October 28 financial results and the October 29 drop in the price of Gilead stock.. First, analysts at the

time all attributed the sales drop to inventory build-up (by the three wholesalers who purchase almost all of the products sold by Gilead). Analysts concluded that Gilead's sales dropped not as a result of a decrease in prescriptions being written for Viread, but because wholesalers during the third quarter were drawing down the inventory they had built up during the second quarter in anticipation of a previously announced June 2003 price increase for Viread.[3] The evidence indicates that the number of Viread prescriptions being written by doctors increased during the third quarter.

Second, there was virtually no discussion of FDA's Warning Letter in the days leading up to the October 29 price drop. The market did not react at all to the initial disclosure of the Warning Letter, which alleged that a single Gilead official had engaged in improper promotion of Viread on a single occasion. Respondents allege that Gilead's misconduct was far more widespread than the single incident that was the subject of the Warning Letter and that Gilead had misleadingly omitted mention of that misconduct. If so, there is no evidence to suggest that investors by October 29, 2003 had become aware of the allegedly widespread misconduct.

Third, although Gilead stock dropped 12% on October 29, it immediately started to recover and by December 2, 2003 had returned to its October 28 price. Respondents have failed to provide any plausible

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[3] Analysts explained that third quarter Viread sales were lower than anticipated because the second-quarter inventory build-up had been larger than analysts had originally anticipated.

explanation for that rapid increase in value. If, as Respondents allege, the market was finally aware by October 29 that a significant portion of Viread sales were being driven by Gilead's improper promotional activities and that the failure to disclose those activities had led to Gilead common stock being overpriced, there is no plausible explanation for the rapid subsequent price rise. There is no reason to believe that market participants suddenly forgot that the stock had previously been overpriced.

Respondent's suit, filed within weeks of the October 29, 2003 price drop, alleged violations of §§ 10(b) and 20(a) of the Securities Exchange Act of 1934, 15 U.S.C. §§ 78j(b) & 78t(a), and SEC Rule 10b-5. The district court dismissed various versions of the complaint on three occasions under Rule 12(b)(6) for failure to adequately allege loss causation.

On the third occasion, in May 2006, the court dismissed the complaint with prejudice. Pet. App. 21a-41a. The court concluded that the connection between the FDA Warning Letter (released on August 7, 2008) and the drop in Gilead stock price nearly three months later was too attenuated to support a loss causation argument. *Id.* at 35a. The court found that the Warning Letter did not cause analysts to predict a decrease in Viread sales; to the contrary, in October and November 2003 analysts predicted that sales would continue to grow. The court deemed such predictions an indication that even after October 28 the market attached little significance to the Warning Letter. *Id.* at 36a. The court also faulted Respondents for failing to plead facts suggesting either that Gilead's failure to

disclose an off-label marketing scheme had inflated the price of Gilead stock or that the publication of the FDA Warning Letter had led practitioners to materially decrease their demand for Viread. *Id.* at 38a n.12.

The Ninth Circuit reversed and remanded. Pet. App. 1a-20a. The court held that a complaint in a securities fraud suit is not subject to rule 12(b)(6) dismissal so long as it pleads "enough facts to state a claim to relief that is plausible on its face." *Id.* at 12a. The court said that the complaint had alleged a plausible theory explaining how the October 29 stock price drop was caused by the Warning Letter issued months earlier. *Id.* at 19a. The court held that a "limited temporal gap" between the time that a misrepresentation is revealed and the subsequent decline in stock price "does not render a plaintiff's theory of loss causation per se implausible." *Id.*

The appeals court concluded that this Court's loss causation ruling in *Dura Pharmaceuticals, Inc. v. Broudo*, 544 U.S. 336 (2005), is inapplicable to cases, as here, in which the plaintiff can point to a drop in stock value that occurs after the alleged misrepresentation is revealed. *Id.* at 15a. The appeals court did not acknowledge the possibility that there might have been other factors that led to the October 29 price drop, nor did it discuss whether the complaint adequately explained why the price drop should be attributed to the disclosure of the Warning Letter and not to some other cause. Nor did it discuss whether Respondent's theory of causation was consistent with the rapid rise of Gilead's stock in the days following October 29. The appeals court indicated that if a district court is

skeptical of a plaintiff's loss causation theory, that "skepticism is best reserved for later stages of the proceedings when the plaintiff's case can be rejected on evidentiary grounds." *Id.* at 17a.

REASONS FOR GRANTING THE PETITION

The petition raises issues of exceptional importance. When it included a provision in the PSLRA that explicitly made "loss causation" an element of any Section 10(b) securities fraud case, Congress made clear that it intended the courts to weed out at the pleadings stage complaints that failed to adequately allege loss causation. Congress did so because it realized that defending even frivolous securities fraud cases can be extremely burdensome, and that those burdens effectively require public companies to settle any case that they cannot dispose of on the pleadings.

The Court in *Dura* recognized the importance of the loss causation requirement as an important pleadings-stage screening device that allows courts to weed out non-meritorious securities law claims. Yet, if the standard adopted by the Ninth Circuit is upheld, virtually any complaint alleging securities fraud can survive a loss causation standard. Under that standard, all a plaintiff need do to avoid dismissal on the pleadings is to avoid the mistake made by the *Dura* plaintiffs – make sure that the complaint alleges that the defendant's alleged misrepresentation became known to the market *before* the defendant's stock price dropped (not afterwards, as in *Dura*). Under the Ninth Circuit standard, it apparently does not matter that (as here) there is no real evidence that the market ever became

aware of the alleged misrepresentation (or even that there ever was a misrepresentation); a plaintiff can survive a loss-causation motion to dismiss by merely alleging that such a disclosure occurred and, assuming the truth of that allegation, by demonstrating that it is "plausible" that such a disclosure might have caused a drop in the defendant's stock price. According to the Ninth Circuit, any more exacting review of the loss causation issue must await a summary judgment motion and/or trial – after the completion of discovery.

As the Petition amply demonstrates, the Ninth Circuit's "plausible on its face" standard is inconsistent with the standard applied by every other federal appeals court in judging motions to dismiss securities fraud complaints. That standard also conflicts with the loss causation standard set forth in *Dura*. Review is warranted to resolve those conflicts.

WLF writes separately to explain why the Ninth Circuit's standard is toothless and will allow plaintiffs' attorneys to craft complaints that can virtually always survive Rule 12(b)(6) motions to dismiss. Such a toothless standard is inconsistent with Congress's intent in adopting the PSLRA, which was designed to ensure that complaints will be dismissed at the pleadings stage unless they provide factual allegations that explain how the plaintiffs' losses were caused by the defendants' alleged misrepresentations. Under the Ninth Circuit's standard, there will be no such dismissals.

Review is also warranted because it is particularly onerous for companies, such as Gilead, whose activities are subject to close federal regulation. The Ninth

Circuit's standard permits plaintiffs to transform virtually any regulatory infraction into a securities fraud case; all they need do is locate a stock price drop that followed disclosure of the infraction, and then allege that the disclosure caused the price drop. This Court in *Stoneridge* warned against permitting use of the securities laws to police a broad range of business activities having little or no connection to the purchase or sale of securities.

Review is also warranted because the pleading standard adopted by the Ninth Circuit is particularly onerous on life-science companies such as Gilead and other relatively new and small companies that are capital intensive. Such companies are particularly prone to being sued for securities fraud because their stock prices tend to be more volatile than are the stock prices of more established public companies. At the same time, such companies tend to be more disrupted by such suits and simply cannot afford to allow the suits to continue if they cannot win dismissal on the pleadings. Yet, the Ninth Circuit's lenient standard will virtually always prevent them from winning dismissal by demonstrating absence of loss causation.

Indeed, this case is a poster child for abusive and frivolous securities fraud litigation. It is very difficult to imagine that there are more than a handful of investors who ever lost money by investing in Gilead common stock. The stock price has been on a virtually unbroken upward trajectory for more than a decade. The October 29, 2003 drop in stock price that is the subject of this lawsuit persisted for less than five weeks, and the initial complaint filed in this very complaint

provides a very plausible explanation (an under-estimation of wholesalers' inventory levels) for that temporary blip. Respondents' far-fetched, alternative explanation for the temporary price drop should be laughed out of court. Instead, it survived the Ninth Circuit's loss causation standard with flying colors – thereby highlighting the need for immediate review of that standard.

I. Review Is Warranted Because the Ninth Circuit's Standard Prevents Securities Fraud Defendants From Obtaining Dismissal on the Pleadings, Contrary to Congress's Intent in Adopting the PSLRA

Congress adopted the PSLRA in 1996 in an effort to eliminate what it viewed as abuses of the securities laws by plaintiffs' lawyers. *Dura*, 544 U.S. at 347. Those "'abusive'" practices included "'the routine filing of lawsuits . . . with only [a] faint hope that the discovery process might lead eventually to some cause of action.'" *Id.* (quoting H.R. Conf. Rep. No. 104-369 p.31 (1995)). While recognizing the need to permit plaintiffs to file complaints without undertaking a "great burden," the Court recognized that "allowing a plaintiff to forgo giving any indication of the economic loss and proximate cause that the plaintiff has in mind would bring about harm of the very sort the statutes seek to avoid." *Id.* The Court explained that relaxing rules requiring the plaintiff to plead facts demonstrating loss causation:

> [W]ould permit a plaintiff 'with a largely groundless claim to simply take up the time of a

> number of other people, with the right to do so representing an *in terrorem* increment of the settlement value, rather than a reasonably founded hope that the [discovery] process will reveal relevant evidence.' . . . Such a rule would tend to transform a private securities action into a partial downside insurance policy.

Id. at 347-48 (quoting *Blue Chip Stamps v. Manor Drug Stores*, 421 U.S. 723, 741 (1975)).

Although the private damage action for violation of § 10(b) of the Securities Exchange Act of 1934 is judicially implied, *Dura* recognized that Congress imposed explicit statutory limits on that right of action when it adopted 15 U.S.C. § 78u-4(b) in 1996 as part of the PSLRA. *Dura*, 544 U.S. at 341. In particular, § 78u-4(b)(4) adds an explicit loss-causation requirement to securities fraud actions: "the plaintiff shall have the burden of proving that the act or omission of the defendant alleged to violate this title caused the loss for which the plaintiff seeks to recover damages."

Dura said that it was unnecessary to decide the precise standard for judging the adequacy of a complaint's loss causation allegations, because even under the most lenient standard – the "fair notice" standard set forth in Fed.R.Civ.P. 8(a)(2) – the plaintiff in that case had failed to allege loss causation adequately. *Dura*, 544 U.S. at 346. The plaintiffs had alleged that the defendant's misrepresentations had caused the plaintiffs to purchased stock at an inflated value. But the Court held that such an allegation is insufficient to allege loss causation, because the

plaintiffs suffered no loss so long as the stock's value was still inflated. *Id.* at 342. Rather, to show loss causation, the plaintiff would have to show that the misrepresentation was later revealed to the market and that the revelation caused a subsequent decrease in stock price. *Id.* at 342-43. Because the plaintiff had not alleged that the misrepresentation had been revealed until after the plaintiffs' stock had declined in value, the Court held that they had failed adequately to allege loss causation. *Id.* at 346-47.

The Ninth Circuit latched onto that one aspect of *Dura* (the reverse order of the stock price decrease and the revelation of the defendant's alleged misrepresentations) and concluded that a plaintiff *always* meets the loss causation pleading requirement by showing that the alleged revelation of the misrepresentation was followed without too much lapse of time by a drop of the defendant's stock price. Pet. App. 19a. The plaintiffs' bald allegation that the revelation "caused" the price drop is sufficient to meet the loss causation pleading standard, the Ninth Circuit held, so long as the complaint pleads "enough facts to state a claim for relief that is plausible on its face." *Id.* at 12a.[4]

That lenient standard essentially does away with the loss causation requirement at the pleadings stage. It provides a road map to any enterprising plaintiffs'

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[4] The Ninth Circuit used the word "plausible" throughout its decision, *see e.g.*, Pet. App. 12a, 17, 18a, 19a, thereby indicating that it was applying a standard roughly akin to the Rule 8(b) notice pleading standard, rather than the stricter pleading standard advocated by Gilead and adopted by each of the other federal appeals courts that has considered the issue.

attorney seeking to file a securities fraud lawsuit following a drop in a company's stock price caused by an earnings report that disappointed some investors. All that the attorney would need to do would be to scour the company's public statements in the months preceding the price drop to find something that could be deemed a misrepresentation. Under the Ninth Circuit's standard, it would then be sufficient to survive a motion to dismiss to allege that the disappointing earnings report constituted the necessary disclosure to the market of the misrepresentation and that the stock had previously been overpriced due to the misrepresentation. Never mind that (as here) there was no public discussion of the alleged misrepresentation at the time of the price drop and that there were other, far more plausible explanations for the drop. It is sufficient, under the Ninth Circuit's standard, to assert that the price drop was an indication that the market finally understood the significance of the prior misrepresentation and was readjusting the stock price accordingly; any issues regarding the accuracy of the claimed causal connection should be deferred until the summary judgment stage, after discovery has been completed. Pet. App. 17a.

That understanding of the loss causation requirement cannot be squared with congressional intent in adopting the PSLRA. One of the purposes of that statute was to ensure that public companies would have the opportunity to win dismissal of insubstantial securities fraud cases at the pleadings stage. *See, e.g.*, H.R. Conf. Rep. No. 104-369, at 44 (1995), *reprinted in* 1995 U.S. Code Cong. & Admin. News 730. The reason that Congress deemed the availability of early dismissals

as critical to the PSLRA's goals is clear: Congress realized that security fraud suits, while often lacking in merit, become too expensive for companies to litigate if the complaint survives a motion to dismiss and huge discovery costs (*e.g.*, costs associated with subjecting senior executives to lengthy depositions) begin to kick in. The loss causation requirement was intended to address that concern by providing a mechanism for dismissal in advance of discovery. *See, e.g.*, 141 Cong. Rec. S9032, 9040 (June 26, 1995) (statement of Senator Domenici) (PSLRA "stops fishing expeditions where lawyers can force thousands of dollars worth of discovery money and demand thousands of company documents before a judge can decide if the complaint really states a cause of action, so that it might be dismissed before the costs of discovery are ever incurred.").

The Ninth Circuit's loss causation standard – in conflict with the standard employed by numerous other federal appeals courts – virtually eliminates the possibility that security fraud lawsuits can be weeded out at the pleadings stage on the basis that the plaintiff has inadequately pleaded loss causation. Review is warranted to resolve that conflict.

II. The Ninth Circuit's Standard Is Particularly Hard on Firms, Such as Gilead, That Are Subject to Extensive Government Regulation

Review is also warranted because the Ninth Circuit's loss causation standard is particularly onerous for companies, such as Gilead, whose activities are

subject to close federal regulation. The Ninth Circuit's standard permits plaintiffs to transform virtually any regulatory infraction into a securities fraud case; all they need do is locate a stock price drop that followed disclosure of the infraction, and then allege that the disclosure caused the price drop.

The pharmaceutical and biotechnology industries are among the most heavily regulated industries in the United States. Gilead is not permitted to market any product to consumers without first obtaining marketing approval from FDA. The application for such approval is a multi-year process that can cost hundreds of millions of dollars. Once marketing begins, companies are subject to intense FDA scrutiny with respect to both their manufacturing practices and their marketing campaigns. As this case illustrates, when FDA officials take issue with one of those practices, they often send Warning Letters expressing their disagreement and threatening to take enforcement action if the practice continues.[5]

According to the Ninth Circuit, FDA's decision to send a Warning Letter to Gilead rendered plausible Respondents' entire theory of loss causation. The appeals court viewed the letter as a sufficient factual basis for Respondents' claims that: (1) Gilead's entire promotional campaign for Viread was in violation of federal food and drug laws; (2) doctors would not have engaged in the entirely legal practice of prescribing Viread for off-label uses but for the illegal promotion;

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[5] It is important to note, however, that the Warning Letter itself does not constitute enforcement action by the agency.

(3) doctors were apparently unaware that some of their Viread prescriptions were for off-label uses, because they supposedly became increasingly reluctant to write Viread prescriptions after learning of the Warning Letter; and (4) the stock price dropped on October 29, 2003 when it suddenly dawned on investors that the Warning Letter released three months earlier was causing doctors to change their views about Viread, even though no one was quoted as saying so in public. The complaint included absolutely no factual allegations to support any one of those four claims. But, from the Ninth Circuit's perspective, the fact that a federal regulatory agency had written a warning letter to the defendant rendered plausible each of those four otherwise unsubstantiated claims.

WLF urges the Court to grant review to make clear that the federal securities laws should not be extended in this manner. The Second Circuit has essentially held that the securities laws are appropriately used as an additional means of ensuring that pharmaceutical and biotechnology companies comply with food and drug laws. The Court warned against such expansion in *Stoneridge*. The plaintiffs in that case sought to hold companies liable for securities fraud under a "scheme liability" theory – even though the defendants had made no statements upon which the plaintiffs relied when investing in Charter Communication's common stock, which later decreased in value. The plaintiffs alleged that the defendants (companies that had engaged in arm's-length business transactions with Charter) had structured those transactions in a manner that assisted Charter in carrying out fraud. In refusing to extend securities

fraud liability to the defendants, the Court warned against expanding securities law so as to regulate the conduct of those not involved in the issuance and sale of securities. *Stoneridge*, 128 S. Ct. at 771. The Court said that § 10(b) "should not be interpreted to provide a private cause of action against the entire marketplace in which the issuing company operates." *Id.*

Similarly, the Court should not permit § 10(b) to serve as an alternative means of enforcing a publicly traded company's regulatory obligations. If FDA becomes convinced that Gilead has failed to comply with provisions of federal food and drug law, it is free to bring appropriate enforcement actions. But FDA's determination that one Gilead official has engaged in improper promotion of Viread does not provide any sort of basis for concluding that Gilead has defrauded its investors. It is possible, of course, that a biotechnology company's stockholders could suffer losses when exposure of a massive fraud committed by the company leads to a collapse of the price of its common stock. But the courts should not permit plaintiffs' lawyers to conflate evidence of such fraud with evidence of a single regulatory violation. Review is warranted to make clear that – contrary to the Ninth Circuit's holding – evidence of a single regulatory violation does not render plausible allegations that a public company's material misrepresentations caused the plaintiffs' loss.

III. This Case Is a Particularly Good Vehicle for Resolving the Question Presented, in Light of Its Status as a "Poster Child" for the Extreme Leniency of the Ninth Circuit's Standard

One look at the appendix to this brief should be sufficient to demonstrate the frivolousness of this lawsuit. The appendix includes a chart that illustrates the virtually uninterrupted rise in the price of Gilead common stock over the past decade.

The October 29, 2003 drop in stock price that is the subject of this lawsuit persisted for less than five weeks, and the initial complaint filed in this very complaint provides a very plausible explanation (an under-estimation of wholesalers' inventory levels) for that temporary blip. Respondents' far-fetched, alternative explanation for the temporary price drop should be laughed out of court. Instead, it survived the Ninth Circuit's loss causation standard with flying colors – thereby highlighting the need for immediate review of that standard.

At a minimum, a standard for evaluating the adequacy of loss causation allegations ought to require the plaintiff to plead a theory that: (1) accounts for the uncontested facts of record; and (2) demonstrates why it is likely that the drop in the defendant's stock price was attributable to the disclosure of the defendant's misrepresentations and not to other potential causes. *See Dura,* 544 U.S. at 342-43 ("When the purchaser subsequently resells such shares, even at a lower price, that lower price may reflect, not the earlier

misrepresentation, but changed economic circumstances, changed investor expectations, new industry-specific or firm-specific facts, conditions, or other events, which taken separately or together account for some or all of the lower price."). The Ninth Circuit applied a standard that examined neither of those factors. Had the Ninth Circuit done so (as would have been required under standards adopted by all other federal appeals courts that have examined the issue), the deficiencies in Respondents' loss causation theory would have been readily apparent.

As noted above, Respondents' loss causation theory fails to account for three uncontested facts. First, analysts in October 2003 all attributed the sales drop to inventory build-up (by the three wholesalers who purchase almost all of the products sold by Gilead). Analysts concluded that Gilead's sales dropped not as a result of a decrease in prescriptions being written for Viread, but because wholesalers during the third quarter were drawing down the inventory they had built up during the second quarter in anticipation of a previously announced June 2003 price increase for Viread.[6] The evidence indicates that the number of Viread prescriptions being written by doctors increased during the third quarter. Respondents' theory (which posits that sales dropped because doctors who had been writing off-label prescriptions all along suddenly became reluctant to do so because of a warning letter that said nothing derogatory about the safety or efficacy of

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[6] Analysts explained that third quarter Viread sales were lower than anticipated because the second-quarter inventory build-up had been larger than analysts had originally anticipated.

Viread), does not explain the facts regarding overstocking and increased prescriptions.

Second, there was virtually no discussion of FDA's Warning Letter in the days leading up to the October 29 price drop. The market did not react at all to the initial disclosure of the Warning Letter, which alleged that a single Gilead official had engaged in improper promotion of Viread on a single occasion. Respondents allege that Gilead's misconduct was far more widespread than the single incident that was the subject of the Warning Letter and that Gilead had misleadingly omitted mention of that misconduct. If so, there is no evidence to suggest that investors by October 29, 2003 had become aware of the allegedly widespread misconduct. In other words, even assuming the accuracy of Respondent's allegation that Gilead was engaged in a massive, illegal marketing campaign, Respondents have failed to provide any factual allegations supporting their contention that the investing public had come to understand that such a campaign existed.

Third, although Gilead stock dropped 12% on October 29, it immediately started to recover and by December 2, 2003 had returned to its October 28 price. Respondents have failed to provide any plausible explanation for that rapid increase in value. If, as Respondents allege, the market was finally aware by October 29 that a significant portion of Viread sales were being driven by Gilead's improper promotional activities and that the failure to disclose those activities had led to Gilead common stock being overpriced, there is no plausible explanation for the rapid subsequent

price rise. There is no reason to believe that market participants suddenly forgot that the stock had previously been overpriced. Yet, Respondents fail to provide any explanation, consistent with their theory of loss causation, that would rationally explain the rapid rise of Gilead stock between October 29 and December 2, 2003.

In sum, had the Ninth Circuit adopted a loss causation standard similar to the standard adopted by other circuits, it would quickly have realized that Respondent's loss causation theory was not even plausible. Review is warranted to determine whether a loss causation standard that fails to weed out claims as implausible as Respondents comports with the PSLRA and *Dura*.

CONCLUSION

Amicus curiae Washington Legal Foundation respectfully requests that the Court grant the petition for a writ of certiorari.

Respectfully submitted,

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APPENDIX

Print Historical Price Chart for Gilead Sciences Inc (GILD) - MSN Money

44.05 ▼ -1.38 -3.04%

Open: **45.45** High: **45.81** Low: **43.75**

Previous Close: **45.43** Volume: **4,165,753**

Eastern Time